

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

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| FSIS DIRECTIVE | 5000.1 Revision 1 | 5/21/03 |
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Verifying an Establishment's Food Safety System

I. PURPOSE

This directive issues FSIS Handbook 5000.1, Verifying an Establishment's Food Safety System. This handbook provides comprehensive direction to FSIS field personnel on how they are to protect the public health by properly verifying an establishment's compliance with the pathogen reduction, sanitation, and HACCP regulations.

II. CANCELLATIONS

FSIS Directive 5000.1, Enforcement of Regulatory Requirements in Establishments Subject to the HACCP System Regulations

FSIS Directive 11,000.1, Sanitation Performance Standards

FSIS Notice 28-02, Actions to be Taken in Establishments Subject to *Salmonella* Testing

III. REASON FOR REISSUANCE

This directive has been rewritten in its entirety as a handbook that also combines instructions from FSIS Directive 11,000.1 and FSIS Notice 28-02. The new handbook provides one comprehensive source for Consumer Safety Inspectors (CSIs) and Consumer Safety Officers (CSOs) to use when verifying or assessing an establishment's food safety system.

IV. REFERENCES

9 CFR parts 416, 417, and 500
9 CFR 310.25 and 381.94

DISTRIBUTION: Inspection Offices; T/A Inspectors;
Plant Mgt; T/A Plant Mgt; TRA; ABB; TSC, Import Offices

OPI: OPPD

V. ATTACHMENTS AND FORMS

Attachment 1--- Handbook 5000.1, Verifying an Establishment's Food Safety System

FSIS Forms 5000-1 through 5000-4 (Available on FAIM)

VI. BACKGROUND

The attachment, Handbook 5000.1, is designed to assist CSIs and CSOs in performing, and in better understanding, their job responsibilities. It includes, at the beginning, tables that CSIs can use to find in the Handbook the verification procedures, documentation instructions, and enforcement actions for specific activities codes. To facilitate use of this handbook, the following walk-through is provided.

A. How do CSIs and CSOs use the Handbook and tables for the Sanitation Performance Standards (SPS) regulations?

CSIs perform the 06D01 procedure when verifying an establishment's compliance with the SPS regulations. For a brief description of how to perform the 06D01 procedure, CSIs should refer to pages I-3 and I-4 of Handbook 5000.1. When a CSI is to perform an 06D01 procedure, the CSI may wish to review pages I-3 through I-21, of the Handbook, to ensure that he or she is familiar with all of the SPS regulatory requirements. Once the CSI is familiar with all the SPS regulatory requirements, he or she will determine which requirements to verify while performing the 06D01 procedure. The CSI can use any method for determining which regulatory requirements he or she plans to verify. The CSI should verify all of the SPS regulatory requirements on an on-going basis. The CSI should coordinate the frequency with the Front-line Supervisor. The Front-line Supervisor will consider such things as compliance history of the establishment, number of plants on the assignment, number of inspectors on the assignment, etc.

When the CSI understands the SPS regulatory requirements and determines which ones he or she will verify, he or she should refer to Table 1. This table references the pages in the Handbook where the CSI can find questions to ask when in verifying that the establishment is meeting each regulatory requirement. These questions will assist the CSI in understanding the thought process he or she should follow in performing the inspection methodology and making regulatory decisions.

If the CSI determines that there is noncompliance with any of the requirements, he or she should refer to pages IV-1 through IV-6 for instructions on documenting the noncompliance. If the noncompliance is part of a trend, the CSI should refer to pages IV-13 through IV-15 for instructions on how and when to link non-compliances. If the CSI decides, based on observations and review of the situation, that issuance of a Notice of Intended Enforcement (NOIE) is necessary, he or she should refer to page IV-14 for instructions.

Page I-30 of Handbook 5000.1, explains the importance of SPS regulatory compliance and the impact that noncompliance can have on other food safety systems. This material is provided particularly for CSOs, although it may be of interest to all FSIS inspection program personnel.

B. How do CSIs and CSOs use the Handbook and tables for the Sanitation Standard Operating Procedure (SOPs) regulations?

When a CSI is to perform one of the Sanitation SOPs procedures (01A01, 01B01, 01B02, 01C01, and 01C02), the CSI should review pages I-21 through I-24, to ensure that he or she understands the correct methodology to use. When performing the Sanitation SOP procedures, the CSI should verify as many of the Sanitation SOP regulatory requirements as possible. The CSI should refer to Table 2 for the specific pages of the Handbook that describe the thought process that he or she should use to verify an establishment's compliance with the Sanitation SOPs regulatory requirements.

If the CSI determines that there is noncompliance with any of the requirements, he or she should refer to pages IV-1 through IV-8 for instructions on documenting the Sanitation SOP noncompliance. If the noncompliance is part of a trend, refer to pages IV-13 through IV-15 for instructions on appropriately linking the noncompliances. If the CSI decides, based on observations and review of the situation, that issuance of an NOIE is necessary, he or she refer to page IV-14. Page IV-20 describes the actions that should be taken when a CSI determines that the establishment shipped adulterated or misbranded product.

Pages I-30 and I-31 of Handbook 5000.1 provide questions that a CSO should ask when assessing the design of the Sanitation SOP. Pages IV-16 and IV-17 provide instructions to the CSOs on documenting their findings during comprehensive food safety assessments.

C. How do CSIs and CSOs use the Handbook and tables for Hazard Analysis and Critical Control Point (HACCP) regulations?

When a CSI is to perform one of the HACCP procedures (03A01, 03B01-03J01, 03B02-03J02), the CSI should review pages II-3 through II-5 to ensure that he or she understands the correct inspection methods to use when performing these procedures. The CSI should refer to Table 3 for the specific pages of the Handbook that describes the HACCP regulatory requirements. These pages describe the thought process that the CSI should use when verifying an establishment's compliance with the HACCP regulatory requirements.

If the CSI determines that there is noncompliance with any of the HACCP requirements, he or she should refer to pages IV-1 through IV-13 for instructions on documenting the HACCP noncompliance. If the noncompliance is part of a trend, refer to pages IV-13 through IV-15 for instructions on appropriately linking the noncompliances. If a CSI determines, based on observations and review of the situation, that issuance of an NOIE is necessary, he or she should refer to page IV-14 for instructions on proceeding with enforcement actions. Page IV-20 describes the actions that should be taken if the CSI determines that the establishment shipped adulterated or misbranded product.

Pages II-31 through II-39 of Handbook 5000.1 provide questions that the CSOs should seek answers to when conducting an assessment of the design of the HACCP systems. Pages IV-16 and IV-17 provide instructions to the CSOs on documenting their findings during the comprehensive food safety assessment.

D. How do CSIs and CSOs use the Handbook and tables the pathogen reduction regulations?

When the CSI is to perform the 05A02 procedure, the CSI should review page III-3 of the Handbook to understand the correct inspection methods to use. The CSI should refer to Table 4 for the specific pages of the handbook that describes the *E. coli* regulatory requirements. These pages describe the thought process the CSI should use when verifying the *E. coli* regulatory requirements.

If the CSI determines there is noncompliance with any of the requirements, he/she should refer to pages IV-1 through IV-13 for instructions on documenting the *E. coli* noncompliance. If the noncompliance is part of a trend, refer to pages IV-13 through IV-15 for instructions on appropriately linking the noncompliances.

If the CSI decides, based on observations and review of the situation, that issuance of an NOIE is necessary, he or she should refer to page IV-14 for instructions on proceeding with enforcement actions.

Pages III-10 and III-11 provide instructions to the CSO on the approach that should be used when conducting an assessment of the *E. coli* written procedures. Pages III-12 through III-15 discuss the role of the CSO as a member of an IDV team for *Salmonella* set failures. Pages IV-16 and IV-17 provide instructions to the CSOs on documenting the results of the comprehensive food safety assessments.

Direct questions to the Technical Service Center.

Philip S. Derfler /s/

Deputy Administrator
Office of Policy and Program Development

Attachments



United States
Department of
Agriculture

Food Safety
and Inspection
Service

FSIS Directive
5000.1

Revision 1

Attachment 1

VERIFYING AN ESTABLISHMENT'S FOOD SAFETY SYSTEM HANDBOOK

INTRODUCTION

LIST OF ACRONYMS

TABLES

CHAPTER I SANITATION

CHAPTER II HACCP

CHAPTER III PATHOGEN REDUCTION ACTIVITIES

CHAPTER IV ENFORCEMENT

INTRODUCTION

If FSIS is to effectively perform its role as a public health regulatory agency, it must have a field force that has a good understanding of how to do its job in a way that will help the Agency meet its public health goals. The intent of this document is to provide comprehensive direction to FSIS field personnel on their responsibilities to protect the public health by effecting the pathogen reduction, sanitation, and HACCP regulations. It provides this direction in a number of ways. First, it provides Consumer Safety Inspectors (CSIs) with the steps they will use to perform the activities necessary to verify that a food safety system is operating in compliance with the regulations and in a way that will result in safe food. It also provides Consumer Safety Officers (CSOs) with the methodology that they will use to verify that the systems are properly designed, in accordance with the regulations. Second, it provides CSIs and CSOs with a series of questions that they are to use in developing a thought process that will help them in assessing the establishment's food safety system and in making regulatory compliance determinations. Third, it is designed to assist the various components of the workforce to understand that they each have different, but complementary, responsibilities in verifying that an establishment's food safety system meets regulatory requirements.

The handbook is set out in four chapters. The first chapter addresses Sanitation Performance Standards and Sanitation SOPs. The second chapter addresses HACCP; the third chapter is on generic *E. coli* and *Salmonella*

Performance Standard Testing; and the fourth chapter covers documentation and enforcement.

The first three chapters provide CSIs with:

1. a description of the verification activities that they are to perform;
2. the questions that they are to consider in performing those verification activities; and
3. some general examples of noncompliance.

The first three chapters also provide CSOs with the methodology that they are to use in conducting a comprehensive assessment of food safety systems in operation. The CSO conducts a comprehensive assessment of all food safety systems by assessing each individual food safety system in the establishment. If the CSO determines that there are design flaws or execution problems in a system, the CSO will determine whether these flaws or problems have an impact on other food safety systems in the establishment by comparing data from one system to another. The CSO has an understanding that the food safety systems should interact with each other to provide a sanitary environment for the manufacture of safe food.

The fourth chapter provides CSIs with:

instructions for completing an accurate and useful noncompliance record;

1. guidance for determining trends and relationships among noncompliances; and
2. an explanation of the Rules of Practice.

In addition, this chapter provides CSOs with instructions on how to document the findings of the comprehensive assessments of food safety systems that they perform. The CSO does not document a record based on an individual finding but completes documentation based on an assessment of his or her findings about the whole system. This documentation can support a conclusion that the food safety systems in operation meet regulatory requirements, or that the food safety systems in operation do not meet regulatory requirements. If an establishment takes corrective and preventive action in response to a CSO's comprehensive assessment, expressed in the form of a 30-day reassessment letter or an NOIE, the CSO will develop a verification plan for the CSI to use to verify the regulatory requirements are met.

This handbook is also for use by Front-line Supervisors and District Office personnel, in conjunction with the IPPS Supervisory Guidelines, to ensure that CSIs and food inspectors understand their roles in appropriately verifying establishments' food safety systems.

To use this handbook, CSIs and CSOs must understand that to appropriately verify food safety systems, they need to employ critical thinking. Each official establishment has a unique food safety system that should be designed to address that establishment's food processing steps and environment. CSIs and CSOs thus must realize that verification is not a one-size-fits-all exercise. The questions presented in this directive are intended to guide both CSIs and CSOs in an approach that focuses on the specific food safety system with which they are confronted.

The examples provided in this handbook are only examples. When following the instructions, methodology, and guidance in this directive, CSIs and CSOs need to use their professional judgment to make informed and factually supportable decisions.

ACRONYMS USED THROUGHOUT THIS DOCUMENT

| | |
|--|-----------|
| Aerobic Plate Counts | APC |
| Association of Official Analytical Chemists | AOAC |
| Consumer Safety Inspectors | CSI |
| Consumer Safety Officers | CSO |
| Critical Control Point | CCP |
| District Manager | DM |
| District Office | DO |
| Environmental Protection Agency | EPA |
| Federal Meat Inspection Act | FMIA |
| Food and Drug Administration | FDA |
| Food Safety and Inspection Service | FSIS |
| Hazard Analysis and Critical Control Point | HACCP |
| In-Depth Verification Review | IDV |
| Inspection System Procedure | ISP |
| Inspector-in-Charge | IIC |
| <i>Listeria monocytogenes</i> | <i>Lm</i> |
| Most Probable Number | MPN |
| National Advisory Committee on Microbiological Criteria for Foods | NACMCF |
| Noncompliance Record | NR |
| Notice of Intended Enforcement Action | NOIE |
| Other Consumer Protection | OCP |

| | |
|--|-------------------|
| Pathogen Reduction Enforcement Program | PREP |
| Performance Based Inspection System | PBIS |
| Poultry Products Inspection Act | PPIA |
| Ready-to-Eat | RTE |
| Sanitation Performance Standards | SPS |
| Sanitation Standard Operating Procedures | Sanitation SOP |
| Supervisory Veterinary Medical Officer | SVMO |
| Technical Service Center | TSC |

Table 1. Sanitation Performance Standards

| If you are to perform an: | What the CSI does | To do this you should consult one or more of the following for each procedure: | If there is noncompliance, you should consult: |
|----------------------------------|---|---|---|
| 06D01 | <p>The CSI should select the SPS requirement or requirements that he or she is going to verify. These requirements are in 9 CFR 416.2 – 416.5.</p> <p>Once the CSI has determined which requirements to verify, he or she will verify regulatory compliance with those requirements by following the instructions on the pages listed for each requirement.</p> | <p>Grounds and Pest Control (416.2(a))</p> <p>Construction (416.2(b))</p> <p>Lighting (416.2(c))</p> <p>Ventilation (416.2(d))</p> <p>Plumbing and Sewage (416.2(e))</p> <p>Sewage Disposal (416.2(f))</p> <p>Water Supply and Water, Ice, and Solution Reuse requirements (416.2(g))</p> <p>Dressing Rooms and Lavatories (416.2(h))</p> <p>Equipment and Utensils (416.3(a)(b)(c))</p> <p>Sanitary Operations (416.4(a)(b)(c))</p> <p>Employee Hygiene (416.5(a)(b)(c))</p> | <p>If the CSI finds that there is <u>noncompliance</u> with one or more of the regulatory requirements, he or she should refer to pages IV-1-6 for instructions on the completion of a noncompliance record.</p> <p>If the CSI finds that there is a <u>trend of noncompliance</u> occurring, he or she should refer to pages IV-13-15 for instructions on NR linkage.</p> <p>If the CSI finds that an <u>enforcement action</u> should be recommended, he or she should refer to pages IV-18-25 for instructions on the Rules of Practice.</p> |

Table 2. Sanitation Standard Operating Procedures

| If you are to perform an: | What the CSI does | To do this you should consult: | If there is noncompliance, you should consult: |
|---|--|--|---|
| 01A01 01B01 01B02 01C01 01C02 | The CSI or food inspector performs one of the verification procedures to determine whether there is regulatory compliance with the implementation, maintenance, corrective action, and recordkeeping requirements of the sanitation SOP regulations. | How to conduct the Sanitation SOP verification procedures AND one of the following sections: Implementation (Monitoring) (416.13) Maintenance (416.14) Corrective action (416.15) Recordkeeping (416.16) | If the CSI finds that there is <u>noncompliance</u> with one or more of the regulatory requirements, he or she should refer to pages IV-1-3 and IV-6-8 for instructions on the completion of a noncompliance record. If the CSI finds that there is a <u>trend of noncompliance</u> occurring, he or she should refer to pages IV-13-15 for instructions on NR linkage. If the CSI finds that an <u>enforcement action</u> should be recommended, he or she should refer to pages IV-18-25 for instructions on the Rules of Practice. |

Table 3. HACCP Verification Procedures

| If you are to perform an: | What the CSI does | To do this, you should rely on: | If there is noncompliance, you should rely on: |
|---|--|--|--|
| 03A01 03B01 – 03J01 03B02 – 03J02 | The CSI performs one of the verification procedures to determine whether there is regulatory compliance with monitoring, verification, corrective action, recordkeeping, and reassessment requirements | How to conduct the HACCP 01 and 02 procedures AND one of the following sections: Verification of hazard analysis Verification of monitoring (417.2(c)(4)), Verification of verification (417.2(c)(7), 417.4(a)(2)(i)(ii)(iii)) Verification of recordkeeping (417.2(c)(6), 417.5(a)(1), 417.5(a)(2), 417.5(a)(3), 417.5(b), 417.5(c), 417.5(d), 417.5(e)(1)(2)) Verification of corrective action (417.3(a), 417.3(b)) Verification of reassessment (417.3(b)(4), 310.25(b)(3)(ii), 381.94(b)(3)(ii), 417.4(a)(3), 417.4(b)) | If the CSI finds that there is <u>noncompliance</u> with one or more of the regulatory requirements, he or she should refer to pages IV-1-3 and IV-8-12 for instructions on the completion of a noncompliance record. If the CSI finds that there is a <u>trend of noncompliance</u> occurring, he or she should refer to pages IV-13-15 for instructions on NR linkage. If the CSI finds that an <u>enforcement action</u> should be recommended, he or she should refer to pages IV-18-25 for instructions on the Rules of Practice. |

Table 4. Pathogen Reduction Verification Procedures

| If you are to perform an: | What the CSI does | To do this you should consult: | If there is noncompliance, you should consult: |
|----------------------------------|---|---|--|
| *05A01 05A02 | The CSI performs the verification procedure to determine whether there is regulatory compliance with the <i>E. coli</i> testing requirements. | <p>How to conduct the verification procedure</p> <p>AND one of the following sections:</p> <p>Verification of sample collection (310.25(a)(2)(ii), 381.94(a)(2)(ii))</p> <p>Verification of sampling frequency (310.25(a)(1)(i), 381.94(a)(1)(i), 310.25(a)(2)(iii), 381.94(a)(2)(iii), 310.25(a)(2)(iv), 381.94(a)(2)(iv), 310.25(a)(2)(v), 381.94(a)(2)(v))</p> <p>Verification of sampling analysis (310.25(a)(1)(ii), 381.94(a)(1)(ii), 310.25(a)(3), 381.94(a)(3))</p> <p>Verification of recording test results (310.25(a)(1)(iii), 381*.94(a)(1)(iii), 310.25(a)(4), 381.94(a)(4))</p> | <p>If the CSI finds that there is <u>noncompliance</u> with one or more of the regulatory requirements, he or she should refer to pages IV-1-3 and IV-12-13 for instructions on the completion of a noncompliance record.</p> <p>If the CSI finds that there is a <u>trend of noncompliance</u> occurring, he or she should refer to pages IV-13-15 for instructions on NR linkage.</p> <p>If the CSI finds that an <u>enforcement action</u> should be recommended, he or she should refer to pages IV-18-25 for instructions on the Rules of Practice.</p> |

*The frontline supervisor reviewing a plant prior to awarding a grant of inspection would perform the 05A01 procedure.

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CHAPTER I - SANITATION

I. Introduction

The FMIA and PPIA both establish that a meat or poultry product is adulterated if it has “been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.” When FSIS personnel inspect the grounds, facilities, and equipment at meat and poultry establishments, they are looking for these insanitary conditions. To determine whether conditions in or around an establishment are insanitary, inspection program personnel must ask the question posed by the Acts: “Could these conditions cause product to be contaminated with filth or cause product to be unsafe?”

There are so many ways that insanitary conditions can cause product to be adulterated that they cannot all be listed. Instead, this Handbook explains the intent of the sanitation regulations and gives examples of some of the ways inspection program personnel can determine whether a meat or poultry establishment is operating under insanitary conditions.

Inspected establishments must meet two sets of regulations concerning sanitation: The Sanitation Standard Operating Procedures (Sanitation SOP) requirements and the Sanitation Performance Standards (SPS). Under the Sanitation SOP requirements, each establishment must develop, implement, and maintain written procedures for the actions it takes daily, before and during operations, to prevent product from being directly contaminated and adulterated. An establishment’s Sanitation SOP typically covers the scheduled, daily pre-operational and operational cleaning and sanitation of equipment and surfaces that may contact product directly. The SPS regulations cover all of the other aspects of plant sanitation that can affect food safety, e.g., pest control, adequate ventilation and lighting, and plumbing systems. Keep in mind that these two sets of regulations overlap somewhat in the plant activities they cover. Also, some establishments may address certain sanitation problems within their HACCP plans.

PART I -- Sanitation Performance Standards

A. What are the general regulatory requirements for the SPS?

Section 416.1 states: *Each official establishment must be operated and maintained in a manner sufficient to prevent the creation of insanitary conditions and to ensure that product is not adulterated.*

The FSIS regulations in 9 CFR 416.2 to 416.5 set forth more specific performance standards that each official establishment must meet to prevent the creation of insanitary conditions that could cause the adulteration of meat and poultry products. These regulations provide the sanitation standards the establishment must meet for the Federal mark of inspection to be applied to its products. Some of the SPS address conditions within or around the establishment (e.g., ventilation, lighting, facility and equipment construction, and maintenance of the grounds). Other SPS address establishment operations and so may be met by an establishment through its Sanitation SOP (e.g., sanitizing of food contact surfaces) or its HACCP plan (e.g., water reuse).

B. What is the relationship between the SPS and the Sanitation SOPs?

The SPS regulations and the Sanitation SOP regulations are set out in separate sections of 9 CFR part 416. Compliance with both, however, is necessary if an establishment is to prevent the creation of insanitary conditions that can cause the adulteration of product. The SPS regulations define generally what the establishment's sanitation efforts must accomplish to maintain the facilities and environment in a sanitary condition. The Sanitation SOP regulations define specifically what the establishment must accomplish to prevent direct contamination of product. Establishment management may choose to address some of the SPS requirements in their written Sanitation SOP or even within their HACCP plan.

CSIs

PART I – Verification Activities for Sanitation Performance Standards

A. In general, how do CSIs verify the Sanitation Performance Standards?

As scheduled by the PBIS, CSIs verify that establishments are complying with the SPS (9 CFR 416.2 – 416.5) and the Sanitation SOPs (9 CFR 416.11 – 416.16).

CSIs may directly observe conditions in the establishment or review records to verify that the establishment is complying with the sanitation regulatory requirements.

9 CFR 416.4(c) requires that an establishment have “documentation substantiating the safety of a chemical’s use in a food processing environment,” 9 CFR 416.2(g) states: “If an establishment uses a municipal water supply, it must make available to FSIS, upon request, a water report, issued under the authority of the State or local health agency, certifying or attesting to the potability of the water supply. If an establishment uses a private well for its water supply, it must make available to FSIS, upon request, documentation certifying the potability of the water supply that has been renewed at least semi-annually.” The other SPS regulations do not require that an establishment maintain records of the procedures that it uses to meet these performance standards. Establishments may incorporate SPS procedures as part of its Sanitation SOPs, in which case they would have to meet the relevant recordkeeping requirements for Sanitation SOPs.

If an establishment’s procedures, or the prerequisite programs that it uses to meet the SPS, are referenced in the hazard analysis, HACCP plan, or Sanitation SOP, the records associated with the procedures are required to be available to FSIS.

Most of the time the CSIs will verify compliance with the SPS regulatory requirements by directly observing the conditions in the establishment.

The 06D01 procedure is used to verify compliance with the SPS requirements in one or more areas of the establishment. If the CSI determines that the establishment is meeting the sanitation regulatory requirements in a particular area of the establishment, the procedure would be documented on the procedure schedule as performed. The CSI must use professional knowledge and good judgment in making the determination whether the SPS requirements are met. The CSI must assess the situation in the establishment and then determine whether the situation creates insanitary conditions, causes adulteration of product, or prevents FSIS from performing inspection. This means that there can

be conditions in the facility that are less than perfect but that would not represent noncompliance with the SPS regulatory requirements because they are not creating insanitary conditions, adulterating product, or preventing FSIS personnel from performing inspection activities.

If the establishment is not meeting the regulatory requirements, it is the CSI's responsibility to initiate the appropriate regulatory control actions to gain regulatory compliance. The examples used in this section are to demonstrate the decisionmaking process that the CSI might use in making regulatory compliance determinations.

PART II -- Verification of the Grounds and Pest Control

A. What is the regulation related to grounds and pest control?

Section 416.2 (a) states: *The grounds about an establishment must be maintained to prevent conditions that could lead to insanitary conditions, adulteration of product, or interfere with inspection by FSIS program employees. Establishments must have in place a pest management program to prevent harborage and breeding of pests on the grounds and within establishment facilities. Pest control substances used must be safe and effective under the conditions of use and not be applied or stored in a manner that will result in the adulteration of product or the creation of insanitary conditions.*

B. How are CSIs to go about verifying the grounds provision of 416.2(a)?

Establishment situations will dictate the level of verification that must be done. Although an establishment must have a pest management program, it need not be written. If establishment management decides to have a written program, it may or may not be included in the Sanitation SOP. If the establishment has included a written pest management program as part of the Sanitation SOP, the CSI verification activities should include reviewing the Sanitation SOP, reviewing the Sanitation SOP records, and directly observing the procedures being monitored. The CSI should verify that the procedures in the Sanitation SOP are being implemented and monitored, that the establishment is documenting in the Sanitation SOP records the monitoring of the procedures, and that any necessary corrective actions are taken.

Verification is much different if the establishment has no written procedures. Since there are no recordkeeping requirements for grounds and pest control, the CSI will verify that the establishment is meeting the requirements by making observations of the outside grounds and pest control. The CSI will check the outside premises to verify that there are no breeding or harborage areas for pests. The CSI will also verify that there is no harborage or breeding of pests within the establishment by inspecting areas of the establishment for evidence of pests. Noncompliance with this regulatory requirement does not have to involve

evidence of pests. The outside grounds and areas within the establishment should be evaluated to verify that no harborage or breeding area exists. If there are areas outside or inside the establishment that are providing harborage or breeding areas for pests, there is noncompliance with this requirement. When verifying this regulatory requirement, the CSI should seek answers to the following questions:

1. Are all outside areas on the official premises maintained in a manner to prevent harborage and breeding of pests?
2. Are all areas within the establishment maintained in a manner to prevent harborage and breeding of pests?
3. Does the establishment have a pest management program?
4. Does the establishment have a written pest management program as part of the Sanitation SOP?
5. If the pest management program is part of the Sanitation SOP, is the establishment monitoring this program?

C. Example of decisionmaking in judging whether there is compliance with this provision.

CSIs will have to use good judgment in making compliance determinations. The CSI must assess all of the information associated with every observation. For example, the CSI observes tall weeds around the facility. Before making a determination about regulatory compliance, the CSI should determine whether the weeds and grass permit harborage and breeding. If the weeds are scattered and do not permit harborage and breeding, there is not noncompliance. If the weeds are so dense as to permit concealment and breeding, there is noncompliance with these regulations.

CSIs will document any noncompliance in a manner that accords with Chapter IV of this document.

D. How are CSIs to go about verifying the pest control substance provision of 416.2(a)?

The second part of this section of the regulations covers the safety, conditions of use, and the application and storage of pest control substances. The CSI will need to gain information about the safety of any such substances the establishment has on hand, the conditions of use, and how they are stored and applied when verifying compliance with these regulations. Some of the information needed could include answers to the following questions:

1. Does the establishment have documentation on file about the safety of the pest control substances?
2. Does the documentation on file include how the pest control substances are to be used?
3. Are the pest control substances being applied as per the conditions and use?

E. Example of decisionmaking in judging whether there is compliance with this provision.

This provision is very straightforward because of the potential for products being adulterated if pest control substances are misused or are not used according to the documentation on file. Therefore, if the establishment does not have documentation on file that the substances are safe and effective, and on how the substances are to be used, there is noncompliance with this provision. If the establishment is applying the substances differently than the documented uses, there is noncompliance. There is also noncompliance if the establishment is storing these substances in a manner that could result in product adulteration.

CSIs will document any noncompliance in a manner that accords with Chapter IV of this document.

PART III -- Construction

A. What is the regulation related to construction?

Section 416.2 (b) states:

(1) Establishment buildings, including their structures, rooms, and compartments must be of sound construction, be kept in good repair, and be of sufficient size to allow for processing, handling, and storage of product in a manner that does not result in product adulteration or the creation of insanitary conditions.

(2) Walls, floors, and ceilings within establishments must be built of durable materials impervious to moisture and be cleaned and sanitized as necessary to prevent adulteration of product or the creation of insanitary conditions.

(3) Walls, floors, ceilings, doors, windows, and other outside openings must be constructed and maintained to prevent the entrance of vermin, such as flies, rats, and mice.

(4) Rooms or compartments in which edible product is processed, handled, or stored must be separate and distinct from rooms or compartments in which

inedible product is processed, handled or stored, to the extent necessary to prevent product adulteration and the creation of insanitary conditions.

B. How are CSIs to go about verifying this regulation?

When verifying compliance with 9 CFR 416.2(b), the CSI should assess the construction of the facility in one or more areas. To do this, the CSI needs to seek answers to questions like the following:

1. Are the buildings, including their structures, rooms, and compartments, kept in good repair, and are they of sufficient size to allow for processing, handling, and storage of product?
2. Are the walls, floors, and ceilings cleaned and sanitized as necessary?
3. Are the structures, rooms, and compartments kept in good repair?
4. Are the rooms and compartments of sufficient size to allow for processing, handling, and storage of product?
5. Are the walls, floors, ceilings, doors, windows, and other outside openings constructed and maintained to prevent the entrance of vermin, such as flies, rats, and mice?
6. Are edible products and inedible products processed, handled, and stored in a manner that prevents product adulteration and the creation of insanitary conditions? Are they processed, handled, and stored separately? If not, is there an opportunity for cross-contamination?

C. Example of decisionmaking in judging whether there is noncompliance with this provision.

The CSI must realize that it is the establishment's responsibility to maintain the facilities in a manner that will not adulterate product or create insanitary conditions. When the CSI is conducting verification procedure 06D01, he or she may observe situations in the establishment in which compliance is not evident. The CSI must evaluate all the information associated with the observation before making a compliance decision. The CSI must remember that the standard used for this requirement is the SPS regulations. The CSI is to assess the condition observed in light of the regulatory requirement and decide whether regulatory requirements have been met.

For example, the CSI observes an area in the establishment that appears to be of insufficient size to allow for storing of product in a manner that prevents insanitary conditions and consequent product adulteration. The CSO should assess the entire situation. If the establishment is able to maintain this area in a

sanitary condition, the establishment is in compliance with the regulation. If there is not adequate space in the area to permit the area to be maintained in a sanitary manner, there is noncompliance with this provision. For example, if the floors and walls cannot be cleaned regularly because of the overcrowded conditions, there is noncompliance with this provision.

CSIs will document any noncompliance in a manner that accords with Chapter IV of this document.

PART IV -- Lighting

A. What is the regulation related to lighting?

Section 416.2 (c) states: *Lighting of good quality and sufficient intensity to ensure that sanitary conditions are maintained and that product is not adulterated must be provided in areas where food is processed, handled, stored, or examined; where equipment and utensils are cleaned; and in hand-washing areas, dressing and locker rooms, and toilets.*

B. How are CSIs to go about verifying this regulation?

When verifying compliance with 9 CFR 416.2(c), the CSI should assess the lighting in the facility in one or more areas. While in these areas verifying these requirements, the CSI needs to seek answers to questions like the following:

1. Are the intensity and quality of lighting adequate for the establishment to determine that the products being processed, handled, stored, or examined are unadulterated, and that sanitary conditions are maintained?
2. Are the intensity and quality of lighting adequate for the establishment to determine that equipment and utensils are appropriately cleaned?
3. Are the intensity and quality of lighting adequate in the hand-washing areas, dressing and locker rooms, and toilets for the establishment to determine that sanitary conditions are maintained?

C. Example of decisionmaking in judging whether there is compliance with this provision.

Since this section of the regulation does not set specific amounts of lighting required, the CSI cannot go to an area of the establishment with a light meter and make a compliance determination. When the CSI is verifying this requirement performing the 06D01 procedure, he or she will have to use good judgment and a sound decisionmaking process to determine compliance. The CSI may observe an area of the establishment that appears to have inadequate lighting. He or she must assess the condition in that area to determine whether

the lighting is adequate for the establishment to ensure that sanitary conditions are maintained, and that product is not adulterated. If this is the case, there is compliance with this provision. If the lighting is not adequate to ensure that sanitary conditions are maintained and that product is not adulterated, there is noncompliance with this provision. For example, if the lighting is not adequate to enable establishment employees to determine whether a substance on product is fecal material, the lighting is inadequate, and there is noncompliance.

CSIs will document any noncompliance in a manner that accords with Chapter IV of this document.

PART V -- Ventilation

A. What is the regulation on ventilation?

Section 416.2 (d) states: *Ventilation adequate to control odors, vapors, and condensation to the extent necessary to prevent adulteration of product and the creation of insanitary conditions must be provided.*

B. How may CSIs go about verifying this regulation?

When verifying compliance with 9 CFR 416.2(d), the CSI should assess the ventilation in the facility in one or more areas. While in these areas verifying these requirements, the CSI needs to seek answers to questions like the following:

1. Is the ventilation adequate to control objectionable odors and vapors that could adulterate product or mask the odor of spoiled or otherwise adulterated product?
2. Is the ventilation adequate to control condensation?

C. Example of decisionmaking in judging whether there is compliance with this provision.

The CSI observes fog or smoke in the cooked meats cooler. When entering the cooler, it appeared that the ventilation was not adequate to control vapors. The CSI assesses the situation and determines that the establishment has placed 10 trays of warm product in the area. The CSI observes that the vapor in the room dissipates before forming any moisture on the ceiling. In this situation, there is not noncompliance. If the vapor coming from the warm product does form moisture on the ceiling, creating an insanitary condition, there is noncompliance with this provision.

CSIs will document any noncompliance in a manner that accords with Chapter IV of this document.

PART VI -- Plumbing and Sewage

A. What are the regulations related to plumbing and sewage?

Section 416.2 (e) states: *Plumbing systems must be installed and maintained to:*

- (1) Carry sufficient quantities of water to required locations throughout the establishment;*
- (2) Properly convey sewage and liquid disposable waste from the establishment;*
- (3) Prevent adulteration of product, water supplies, equipment, and utensils and prevent the creation of insanitary conditions throughout the establishment;*
- (4) Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor;*
- (5) Prevent back-flow conditions in and cross-connection between piping systems that discharge waste water or sewage and piping systems that carry water for product manufacturing; and*
- (6) Prevent the backup of sewer gases.*

Section 416.2 (f) states: *Sewage must be disposed into a sewage system separate from all other drainage lines or disposed of through other means sufficient to prevent backup of sewage into areas where product is processed, handled, or stored. When the sewage disposal system is a private system requiring approval by a State or local health authority, the establishment must furnish FSIS with the letter of approval from that authority upon request.*

B. How are CSIs to go about verifying this regulation?

When verifying compliance with 9 CFR 416.2(e) and (f), the CSI should assess the plumbing in the facility in one or more areas. While in these areas verifying these requirements, the CSI needs to seek answers to questions like the following:

1. Are sufficient quantities of water provided throughout the establishment?
2. Does the plumbing system properly convey sewage and disposable waste from the establishment?
3. Does the plumbing system provide adequate floor drainage?

4. Is the plumbing installed to prevent back-flow conditions and cross-connections between piping systems that discharge waste water or sewage and piping systems that carry water for product manufacturing?

5. Is the plumbing installed to prevent the backup of sewer gases?

6. Is the sewage disposed into a sewage system separate from all other drainage lines or other means to prevent backup of sewage into areas where product is processed, handled, or stored?

7. If the sewage disposal system is a private system requiring approval by a State or local health authority, is the letter of approval available to FSIS upon request?

C. Example of decisionmaking in judging whether there is compliance with this provision.

The CSI is in the area of the plant where several water-cooking units are being drained simultaneously. There is a gutter drain that the water is drained into, and the end of a cleanup hose is submerged in the gutter drain. The CSI thinks there is noncompliance with this provision but decides to evaluate the situation further. The CSI finds a vacuum breaker at the cleanup station to prevent back siphonage. The CSI determines there is not noncompliance. If there had been nothing to prevent back siphonage, there would be noncompliance with this provision.

CSIs will document any noncompliance in a manner that accords with Chapter IV of this document.

PART VII -- Water Supply and Water, Ice, and Solution Reuse

A. What is the regulation related to water supply?

Section 416.2 (g) states: (1) A supply of running water that complies with the National Primary Drinking Water regulations (40 CFR part 141), at a suitable temperature and under pressure as needed, must be provided in all areas where required (for processing product, for cleaning rooms and equipment, utensils, and packaging materials, for employee sanitary facilities, etc.). If an establishment uses a municipal water supply, it must make available to FSIS, upon request, a water report, issued under the authority of the State or local health agency, certifying or attesting to the potability of the water supply. If an establishment uses a private well for its water supply, it must make available to FSIS, upon request, documentation certifying the potability of the water supply that has been renewed at least semi-annually.

B. How are CSIs to go about verifying this regulation?

When verifying compliance with 9 CFR 416.2(g), the CSI should check the water in the facility in one or more areas.

While in these areas, the CSI needs to seek answers to questions like the following:

1. Does the establishment have documentation that the water in the establishment complies with the EPA's National Primary Drinking Water Regulations?
2. Is there adequate water pressure, at a suitable temperature, in all areas where required, for example, for processing product; for cleaning rooms and equipment, utensils, and packaging materials; for employee sanitary facilities?
3. If the establishment uses a municipal water supply, does it have a water report issued under the authority of the State or local health agency certifying or attesting to the potability of the water supply?
4. If the establishment uses a private well for its water supply, does the establishment have on file documentation certifying the potability of the water supply that is renewed semi-annually?

C. What is the regulation related to reuse of water, ice, and solutions for RTE product?

Section 416.2(g)(2) states: *Water, ice, and solutions (such as brine, liquid smoke, or propylene glycol) used to chill or cook ready-to-eat product may be reused for the same purpose, provided that they are maintained free of pathogenic organisms and fecal coliform organisms and that other physical, chemical, and microbiological contamination have been reduced to prevent adulteration of product.*

D. How are CSIs to go about verifying this regulation?

The CSI should determine whether the establishment is reusing water, ice, or solutions (such as brine, liquid smoke, or propylene glycol) to chill or cook RTE product.

If the establishment is reusing water, ice, or solutions to cook or chill RTE products, the CSI needs to seek answers to these type of questions:

1. Are water, ice, and solutions that are reused maintained free of pathogenic organisms and fecal coliform organisms?

2. Is other physical, chemical, and microbiological contamination reduced to prevent adulteration of product?

3. Did the establishment consider water, ice, and solution reuse in the hazard analysis?

4. If the establishment considered water, ice, and solution reuse in the hazard analysis and found a food safety hazard reasonably likely to occur, is there a CCP in the HACCP plan to address this hazard?

E. What is the regulation related to reuse of water, ice, and solutions for raw product?

Section 416.2(g) states: *(3) Water, ice, and solutions to chill or wash raw product may be reused for the same purpose provided that measures are taken to reduce physical, chemical, and microbiological contamination so as to prevent contamination or adulteration of product. Reuse that which has come into contact with raw product may not be used on ready-to-eat product.*

(4) Reconditioned water that has never contained human waste and that has been treated by an onsite advanced wastewater treatment facility may be used on raw product, except in product formulation, and throughout the facility in edible and inedible production areas, provided that measures are taken to ensure that this water meets the criteria prescribed in paragraph (g)(1) of this section. Product, facilities, equipment, and utensils coming in contact with this water must undergo a separate final rinse with non-reconditioned water that meets the criteria prescribed in paragraph (g)(1) of this section.

(5) Any water that has never contained human waste and that is free of pathogenic organisms may be used in edible and inedible product areas, provided it does not contact edible product. For example, such reuse water may be used to move heavy solids, to flush the bottom of open evisceration troughs, or to wash antemortem areas, livestock pens, trucks, poultry cages, picker aprons, picking room floors, and similar areas within the establishment.

(6) Water that does not meet the use conditions of paragraphs (g)(1) through (g)(5) of this section may not be used in areas where edible product is handled or prepared or in any manner that would allow it to adulterate edible product or create insanitary conditions.

F. How are CSIs to go about verifying this regulation?

CSIs should review sections of the establishment's Sanitation SOP or HACCP plan that address water supply and water, ice, and solution reuse before considering the actual establishment condition. They should assess program

effectiveness pertaining to water supply and water, ice, and solution reuse through observing actual establishment conditions and considering the following:

1. Is the potable water supply from a municipal source? If not, does the certification or other documentation on file evidence that the establishment's potable water supply meets the EPA's primary potability requirements for sources of drinking water?

2. Is there an adequate supply of potable water in the establishment?

3. Are the ice-making equipment, rooms, and augers maintained in good repair and sanitary condition?

4. Is water, ice, and solutions reuse accomplished properly and according to 9 CFR 416.2?

NOTE: The regulations state that water may be reused "for the same purpose." This means that water used to wash or otherwise process raw product may be reused to wash or otherwise process raw product, even at a different point in processing, provided that "measures are taken to reduce physical, chemical, or microbiological contamination." For example, an establishment could reuse poultry chiller water in a scalding tank. Furthermore, water used to process RTE product could be reused to wash or process raw product. But water used to process raw product may not be reused to process RTE product. For example, an establishment could not reuse poultry chiller water for cooking or cooling packaged RTE product.

PART VIII -- Dressing Rooms and Lavatories

A. What is the regulation related to dressing rooms and lavatories?

Section 416.2 (h) states: *(1) Dressing rooms, toilet rooms and urinals must be sufficient in number, ample in size, conveniently located, and maintained in a sanitary condition and in good repair at all times to ensure cleanliness of all persons handling any product. They must be separate from the rooms and compartments in which products are processed, stored, or handled.*

(2) Lavatories with running hot and cold water, soap, and towels must be placed in or near toilet and urinal rooms and at such other places in the establishment as necessary to ensure cleanliness of all persons handling any product.

(3) Refuse receptacles must be constructed and maintained in a manner that protects against the creation of insanitary conditions and the adulteration of product.

B. How are CSIs to go about verifying this regulation?

When verifying compliance with 9 CFR 416.2(h), the CSI should assess the dressing rooms, toilet rooms, and urinal rooms. The CSI should also assess the lavatories in one or more areas of the establishment. While in these areas verifying these requirements, the CSI needs to seek answers to questions like the following:

1. Are the dressing rooms, toilet rooms, and urinals sufficient in number, ample in size, conveniently located, and maintained in a sanitary condition and in good repair?
2. Are dressing rooms, toilet rooms, and urinals separate from the rooms and compartments in which products are processed, stored, or handled?
3. Are there lavatories with running hot and cold water, soap, and towels placed in or near toilet and urinal rooms and other places in the establishment as necessary?
4. Are refuse receptacles constructed and maintained in a sanitary manner?

C. Example of decisionmaking in judging whether there is compliance with this provision.

The CSI is in an area of the establishment where edible product is being handled. There are several employees working in this rather large room. The CSI observes that there is only one lavatory close by. The CSI thinks that there may be noncompliance with this requirement but decides to evaluate the situation further before making a compliance determination. The CSI observes that the employees are handling product, and when employees' hands are contaminated, they go to the lavatory and wash their hands. The CSI determines that in this situation, there is not noncompliance. If the employees were not washing their hands because the lavatory was not appropriately located in this area, there would be noncompliance with this provision.

CSIs will document any noncompliance in a manner that accords with Chapter IV of this document.

PART IX -- Equipment and Utensils

A. What is the regulation related to equipment and utensils?

Section 416.3 states: *(a) Equipment and utensils used for processing or otherwise handling edible product or ingredients must be of such material and construction to facilitate thorough cleaning and to ensure that their use will not cause the adulteration of product during processing, handling, or storage.*

Equipment and utensils must be maintained in sanitary condition so as not to adulterate product.

(b) Equipment or utensils must not be constructed, located, or operated in a manner that prevents FSIS inspection program employees from inspecting the equipment or utensils to determine whether they are in sanitary condition.

(c) Receptacles used for storing inedible material must be of such material and construction that their use will not result in the adulteration of any edible product or in the creation of insanitary conditions. Such receptacles must not be used for storing any edible product and must bear conspicuous and distinctive marking to identify permitted uses.

B. How are CSIs to go about verifying this regulation?

When verifying compliance with 9 CFR 416.3, the CSI should assess the equipment and utensils in one or more areas of the establishment. While in these areas, the CSI should also verify that the receptacles used for storing inedible material meet the regulatory requirements. While in these areas verifying these requirements, the CSI needs to seek answers to questions like the following:

1. Are the equipment and utensils used for processing and otherwise handling edible product or ingredients of material and construction that facilitates thorough cleaning?

2. Are equipment or utensils constructed, located, or operated in a manner that prevents inspection program personnel from inspecting the sanitary condition of the equipment or utensils?

3. Are receptacles used for storing inedible material constructed of materials that can be maintained in a sanitary manner?

4. Are receptacles used for storing inedible products marked conspicuously and distinctively to identify permitted uses?

C. Example of decisionmaking in judging whether there is compliance with this provision.

The CSI observes a closed system that had not been disassembled for cleaning. The CSI does not believe that there is noncompliance with this provision but decides to assess the situation further before making a compliance determination. By looking into the matter, he or she determines that this system is cleaned-in-place, and that there are inspection openings at every change of direction to allow for verification of the effectiveness of the sanitation procedures. The CSI inspects the system through the openings and finds that the closed

system is being adequately cleaned. There is compliance with this provision. If the closed system did not permit inspection or was creating insanitary conditions, there would be noncompliance with this provision. The CSI should keep in mind that the establishment may choose to meet the requirements of 9 CFR 416.3 through its Sanitation SOP or through other activities it conducts to comply with the SPS regulations.

CSIs will document any noncompliance in a manner that accords with Chapter IV of this document.

PART X -- Sanitary Operations

A. What is the regulation related to sanitary operations?

Section 416.4 states: *(a) All food-contact surfaces, including food-contact surfaces of utensils and equipment, must be cleaned and sanitized as frequently as necessary to prevent the creation of insanitary conditions and the adulteration of product.*

(b) Non-food-contact surfaces of facilities, equipment, and utensils used in the operation of the establishment must be cleaned and sanitized as frequently as necessary to prevent the creation of insanitary conditions and the adulteration of product.

(c) Cleaning compounds, sanitizing agents, processing aids, and other chemicals used by an establishment must be safe and effective under the conditions of use. Such chemicals must be used, handled, and stored in a manner that will not adulterate product or create insanitary conditions. Documentation substantiating the safety of a chemical's use in a food-processing environment must be available to FSIS inspection program employees for review. [In most cases the documentation will be "Material Safety Data Sheets."]

(d) Product must be protected from adulteration during processing, handling, storage, loading, and unloading at and during transportation from official establishments.

B. How are CSIs to go about verifying this regulation?

When verifying compliance with 9 CFR 416.4, the CSI should assess how the equipment and utensils in one or more areas of the establishment are cleaned and handled. The CSI should assess whether products are protected from adulteration during processing, handling, storage, loading, and unloading, and during transportation. The CSI should also assess use, handling, and storage of cleaning compounds, sanitizing agents, processing aids, and other chemicals in the establishment. The CSI needs to seek answers to questions like the following:

1. Are all food-contact surfaces of facilities, equipment, and utensils cleaned and sanitized as frequently as necessary to prevent insanitary conditions and the adulteration of product?

NOTE: Many establishments will comply with the requirements of Section 416.4(a) through Sanitation SOP activities.

2. Are non-food contact surfaces of facilities, equipment, and utensils used in the operation of the establishment cleaned and sanitized as necessary to prevent the creation of insanitary conditions and the adulteration of product?

3. Are the cleaning compounds, sanitizing agents, processing aids, and other chemicals used by the establishment safe and effective under the conditions of use?

4. Does the establishment have documentation substantiating the safety of a chemical's use in a food processing environment?

5. Does the establishment protect product from adulteration during processing, handling, storage, loading and unloading, and transportation from official establishments?

6. If the establishment uses extended clean-up procedures, are these procedures included in the Sanitation SOP?

C. Example of decisionmaking in judging whether there is compliance with this provision.

The CSI observes several vats of meat in the raw product storage area that are not covered. There are several other vats of meat stored in this area that are covered. The CSI thinks that there might be noncompliance with this provision but decides to evaluate the situation further before making a compliance determination. The CSI looks at the overhead in the area and does not observe any conditions that would constitute insanitation or that would cause product adulteration. The CSI observes an employee come into the area and take a vat of product out of this area. The CSI follows the employee to determine whether the product needs to be protected while being transferred to another area. The CSI finds no conditions that would require the product to be covered during transit. Therefore, the CSI determines that there is not noncompliance with this provision. If the CSI had observed that there was a condition in the establishment that could adulterate product during storage or handling, there would be noncompliance with this provision.

CSIs will document any noncompliance in a manner that accords with Chapter IV of this document.

PART XI -- Employee Hygiene

A. What is the regulation related to employee hygiene?

Section 416.5 states: *(a) Cleanliness. All persons working in contact with product, food-contact surfaces, and product-packaging materials must adhere to hygienic practices while on duty to prevent adulteration of product and the creation of insanitary conditions.*

(b) Clothing. Aprons, frocks, and other outer clothing worn by persons who handle product must be of material that is disposable or readily cleaned. Clean garments must be worn at the start of each working day and garments must be changed during the day as often as necessary to prevent adulteration of product and the creation of insanitary conditions.

(c) Disease control. Any person who has or appears to have an infectious disease, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination, must be excluded from any operations which could result in product adulteration and the creation of insanitary conditions until the condition is corrected.

B. How are CSIs to go about verifying this regulation?

When verifying compliance with 9 CFR 416.5, the CSI should assess employee hygiene in one or more areas of the establishment. While in these areas verifying these requirements, the CSI needs to seek answers to questions like the following:

1. Are the persons in contact with product, food-contact surfaces, and product-packaging materials adhering to hygienic practices?
2. Are aprons, frocks, and other outer clothing worn by persons who handle product made of material that is disposable or readily cleaned?
3. Are clean garments worn at the start of the day and changed during the day as often as necessary?
4. Are persons who appear to have an infectious disease, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination excluded from any operations that could result in product adulteration and the creation of insanitary conditions?

NOTE: The regulations pertaining to employee hygiene also apply to FSIS personnel. As representatives of a public health agency, it is imperative that inspection program personnel lead through example and follow all provisions in 9

CFR 416.3 and 416.5 during the performance of their official duties within federally inspected meat and poultry product establishments. Inspection program personnel must adhere to establishments' special requirements as well. In this manner, FSIS can aid in maintaining the sanitary conditions inside the facilities to which FSIS personnel are assigned. These regulations do not require establishment employees to wear frocks or smocks, but require outer clothing to be of material that is disposable or readily cleanable. If inspection program personnel have questions about an employee having an infectious disease, he or she should discuss this with plant management. Inspection program personnel are not trained to diagnose infectious diseases. If the establishment has requirements that are more stringent than the SPS requirements, inspection program personnel are expected to follow those requirements.

C. Example of decisionmaking in judging whether there is compliance with this provision.

The CSI observes an employee preparing to start to work in the raw product area. The employee puts on an apron. The CSI observes that the apron is dirty from the previous day's production. The CSI thinks that there is noncompliance with this provision but decides to evaluate this situation further before making a compliance determination. He observes the employee go to the washroom and clean the apron thoroughly before starting to work. The CSI determines that there is not noncompliance with this provision. If the employee does not clean the apron appropriately before going to work, there would be noncompliance with this provision.

CSIs will document any noncompliance in a manner that accords with Chapter IV of this document.

PART XII -- Sanitation SOPs

A. What are the written Sanitation SOP Procedures?

The establishment has the responsibility to develop, implement, and maintain written Sanitation SOPs. The basic regulatory requirements are described in 9 CFR 416.12. At the time inspection is granted, the establishment must have a Sanitation SOP that meets these requirements. The CSI performs the 01A01 procedure to verify that the written procedures meet the basic regulatory requirements. The CSI determines when it is necessary to perform the 01A01 procedure. There are four Sanitation SOP regulatory requirements. The four requirements are: implementation and monitoring, maintenance, recordkeeping, and corrective action. If the CSI determines that the Sanitation SOP does not meet the regulatory requirements specified in 9 CFR 416.12, he or she should contact the DO for direction. The DO will provide direction as to whether the CSI should issue a 30-day reassessment letter, or whether the DO will institute an enforcement action specified in the Rules of Practice, 9 CFR part 500.

PART XIII -- Inspection Procedures

A. What are the inspection procedures for the Sanitation SOPs?

There are two Sanitation SOP procedures for pre-operational sanitation verification (01B01/01B02) and two Sanitation SOP procedures for operational sanitation verification (01C01/01C02). The CSI performs these procedures to verify that the establishment is meeting the Sanitation SOP regulatory requirements. Those requirements are:

1. Implementation and monitoring of Sanitation SOP (416.13);
2. Maintenance of Sanitation SOP (ensuring its effectiveness) (416.14);
3. Sanitation SOP corrective actions (416.15); and
4. Sanitation SOP recordkeeping (416.16)

B. How do CSIs conduct the 01B01 procedures?

The 01B01 Sanitation SOP procedure is the pre-operational recordkeeping procedure. This recordkeeping procedure instructs the CSI to verify the daily documentation of the establishment's implementation and monitoring of the Sanitation SOP procedures and required corrective actions.

When the CSI performs the 01B01 procedure, he or she should review the Sanitation SOP and the establishment's pre-operational Sanitation SOP records to verify that the establishment is meeting the regulatory requirements for pre-operational sanitation.

The CSI should review the Sanitation SOP to become knowledgeable about the procedures in it. The CSI should review the daily pre-operational Sanitation SOP records to verify that the establishment is following the pre-operational procedures, that the monitoring activities are conducted at the specified frequency, that the corrective action requirements are met, and that records are being authenticated by the establishment employee responsible for implementation and monitoring of the Sanitation SOP. This is a recordkeeping procedure and the CSI should be reviewing pre-operational records only to determine if the establishment is meeting the regulatory requirements.

C. How do CSIs conduct the 01C01 procedures?

When the CSI performs the 01C01 procedure, he or she should review the establishment's operational sanitation records to verify that the regulatory requirements for operational sanitation are met.

The CSI should review the Sanitation SOP to become knowledgeable with the procedures in it. The CSI should review the Sanitation SOP operational records to verify that the establishment is following the operational procedures in the Sanitation SOP, that the monitoring activities are conducted at the specified frequency, that the corrective action requirements are met, and that records are being authenticated by the establishment employee responsible for implementation and monitoring of the Sanitation SOP.

D. What are CSIs to do when performing the 01B02 procedure?

The 01B02 Sanitation SOP procedure is a review and observation procedure for verifying pre-operational sanitation. When performing the review and observation procedure, the CSI will verify all four requirements: implementation and monitoring, maintenance, corrective actions, and recordkeeping.

The CSI should review the Sanitation SOP to ensure that he or she is knowledgeable about the current written procedures.

NOTE: The CSI needs to understand the procedures in the Sanitation SOP that the establishment is implementing to prevent direct contamination or other adulteration of product. The CSI should become familiar with any monitoring procedures and frequencies that may be included in the Sanitation SOP. Without this knowledge the CSI will not be able to verify regulatory compliance.

If the CSI is to perform the 01B02 procedure and has reviewed the Sanitation SOP, he or she should verify the pre-operational sanitation requirements by inspecting direct contact surfaces in one or more areas of the establishment, observing the establishment perform the monitoring procedures, and comparing his or her findings with what the establishment has documented.

NOTE: When the CSI is performing the 01B02 procedure, he or she should inspect direct contact surfaces and observe the establishment conduct its monitoring procedures when possible.

4. It is possible that the CSI might be performing his or her review and observation procedure at the same time the establishment is monitoring their pre-operational procedures. This provides an excellent opportunity for the CSI to perform the observation part of this procedure. In some cases, the establishment might conduct its monitoring of the implementation of the Sanitation SOP procedures before inspection program personnel arrive at the establishment. In these situations, the CSI should seek direction from supervisory personnel as to how frequently he or she should directly observe the establishment conduct monitoring.

NOTE: The supervisor should consider several factors when making this decision: 1) establishment compliance history, 2) documentation in the FSIS file, and 3) information from Sanitation SOP records.

E. What are CSIs to do when performing the 01C02 procedures?

The CSI should perform the 01C02 procedure the same way as he or she conducts the 01B02, except this procedure is conducted during operations. Again, the CSI should review the Sanitation SOP to become familiar with all the procedures in the Sanitation SOP.

The CSI should verify that the establishment is meeting the Sanitation SOP regulatory requirements for operational sanitation by:

1. inspecting one or more areas of the establishment to ensure procedures are effective in preventing direct contamination or other adulteration of product,
2. observing the establishment perform the monitoring procedures, and
3. comparing the findings to what the establishment has documented.

It might be difficult for the CSI to observe the establishment conducting its monitoring because 9 CFR 416.13 requires that the establishment monitor the procedures in the Sanitation SOP daily. The CSI might not be available to observe that activity when it is occurring.

PART XIV – Implementation and Monitoring

A. What is the implementation and monitoring regulation?

Section 416.13 states: *Each official establishment shall conduct the pre-operational procedures in the Sanitation SOPs before the start of operations.*

(a) Each official establishment shall conduct all other procedures in the Sanitation SOPs at the frequencies specified.

(b) Each official establishment shall monitor daily the implementation of the procedures in the Sanitation SOPs.

B. What are some questions the CSI should consider when performing verification activities for this regulation?

When verifying compliance with 9 CFR 416.13, the CSI should seek answers to the following type of questions:

1. Is the establishment implementing the pre-operational procedures in the Sanitation SOP prior to the start of operations?
2. Are direct contamination or adulteration of product or unclean direct product contact surfaces observed by FSIS or the establishment?

3. Is the establishment conducting the procedures in the Sanitation SOP as specified?

4. Does the Sanitation SOP contain monitoring frequencies?

5. If the Sanitation SOP does not contain monitoring frequencies, is the establishment monitoring the implementation of the procedures in the Sanitation SOP daily?

NOTE: If environmental sampling is included in the Sanitation SOP, the CSI should verify that the establishment is following those procedures. The CSI should observe the establishment collecting samples, should review sample results, and verify that the corrective actions specified in the Sanitation SOP for results that do not meet the criteria of the procedures are taken when necessary. This verification should be completed as part of the Sanitation SOP verification procedures.

CSIs will document any noncompliance in a manner that accords with Chapter IV of this document.

PART XV -- Maintenance

A. What is the maintenance regulation?

Section 416.14 states: *Each official establishment shall routinely evaluate the effectiveness of the Sanitation SOPs and the procedures therein in preventing direct contamination or adulteration of product(s) and shall revise both as necessary to keep them effective and current with respect to changes in facilities, equipment, utensils, operations, or personnel.*

B. What are some questions the CSI should consider when performing verification activities for this regulation?

When verifying compliance with 9 CFR 416.14, the CSI will seek answers to questions of the following type:

1. Has the establishment routinely evaluated the effectiveness of the Sanitation SOPs in preventing direct contamination or adulteration of product? Is the establishment doing environmental testing or taking other steps to assess whether its Sanitation SOPs are effective?

2. If changes were made in facilities, equipment, utensils, operations, or personnel, have the Sanitation SOPs been revised to keep them effective?

NOTE: Construction and removal of walls, ceilings, and floors may cause harborage sites for *L. monocytogenes* to be dislodged from otherwise protected areas. The CSI should ask whether the establishment has stepped up its on-

going verification activity to ensure that the current Sanitation SOP or other procedures are adequate to find insanitary conditions.

3. Does the establishment routinely review the Sanitation SOP records to determine if there are trends occurring showing the Sanitation SOP needs revising?

C. What is an example of noncompliance?

- Changes were made in the facilities, equipment utensils, operations, or personnel, and the Sanitation SOP is no longer effective in preventing direct contamination or adulteration of product.

CSIs will document any noncompliance in a manner that accords with Chapter IV of this document.

PART XVI – Corrective Actions

A. What is the regulation on corrective actions?

Section 416.15 states: (a) *Each official establishment shall take appropriate corrective action(s) when either the establishment or FSIS determines that the establishment's Sanitation SOPs or the procedures specified therein, or the implementation or maintenance of the Sanitation SOPs, may have failed to prevent direct contamination or adulteration of product(s).*

(b) *Corrective actions include procedures to ensure appropriate disposition of product(s) that may be contaminated, restore sanitary conditions, and prevent the recurrence of direct contamination or adulteration of product(s), including appropriate reevaluation and modification of the Sanitation SOPs and the procedures specified therein or appropriate improvements in the execution of the Sanitation SOPs or the procedures specified therein.*

B. What are some questions the CSI should consider when performing verification activities for this regulation?

When verifying compliance with 9 CFR 416.15, the CSI should seek answers to the following:

1. If there is direct contamination or other adulteration of product, does the establishment implement corrective actions that restore sanitary conditions, prevent recurrence, and make appropriate disposition decisions regarding any product that may be contaminated?

2. Do the corrective actions include the reevaluation and modification of the Sanitation SOPs or improvements in the execution of the procedures when necessary?

NOTE: If the establishment is monitoring the pre-operational sanitation procedures, finding noncompliance, taking the corrective actions required in 9 CFR 416.15, and the CSI is not finding direct contact surfaces that may cause adulterated or contaminated product, the CSI should focus on whether the overall implementation of the Sanitation SOP is effective in preventing direct contamination or other adulteration of product. The CSI should not focus on the fact that the preventive measures being used are the same as previous preventive measures used by the establishment. When the CSI finds direct contact surfaces unclean or direct contamination or adulteration of product, he or she should take a regulatory control action. That regulatory control action should not be relinquished until the establishment has proposed an acceptable preventive measure. There is no noncompliance if the establishment finds such conditions and takes the appropriate corrective actions. These corrective actions include restoring sanitary conditions, making appropriate disposition of product, and implementing measures to prevent recurrence. This thought process would not pertain to situations in which product became contaminated. Since the Sanitation SOP must contain procedures to prevent direct contamination or adulteration of product, FSIS would expect the establishment to have procedures in place to prevent the contamination of product.

C. What are some examples of noncompliance?

- The Sanitation SOP failed to prevent direct contamination or other adulteration of product, and the establishment did not implement corrective actions to ensure appropriate disposition of product.
- The Sanitation SOP failed to prevent direct contamination or other adulteration of product, and the establishment did not implement corrective actions to restore sanitary conditions.
- The Sanitation SOP failed to prevent direct contamination or other adulteration of product, and the establishment did not implement corrective actions to prevent recurrence of direct contamination or adulteration of product. This may lead to a trend of repeated noncompliances.

CSIs will document noncompliance in a manner that accords with Chapter IV of this document.

PART XVII -- Recordkeeping

A. What is the regulation on recordkeeping?

Section 416.16 states: (a) *Each official establishment shall maintain daily records sufficient to document the implementation and monitoring of the Sanitation SOPs*

and any corrective actions taken. The establishment employee(s) specified in the Sanitation SOPs as being responsible for the implementation and monitoring of the procedure(s) specified in the Sanitation SOPs shall authenticate these records with his or her initials and the date.

(b) Records required by this part may be maintained on computers provided the establishment implements appropriate controls to ensure the integrity of the electronic data.

(c) Records required by this part shall be maintained for at least 6 months and made accessible available to FSIS. All such records shall be maintained at the official establishment for 48 hours following completion, after which they may be maintained off-site provided such records can be made available to FSIS within 24 hours of request.

B. What are some questions the CSI should consider when performing verification activities for this regulation?

When verifying compliance with 9 CFR 416.16, the CSI should seek answers to the following type of questions:

1. Is the establishment maintaining daily records sufficient to document the implementation and monitoring of the Sanitation SOPs and any corrective actions taken?

2. Is an establishment employee responsible for the implementation and monitoring of the procedures in the Sanitation SOPs and authenticating the records with his or her initials and date?

3. If records are being maintained on computers, are there controls to ensure the integrity of the electronic data?

4. Are Sanitation SOP records being maintained for at least 6 months and available to FSIS?

5. Are Sanitation SOP records kept off-site 48 hours after completion? If so, are they available to FSIS within 24 hours of request?

6. Do the Sanitation SOP records accurately reflect the sanitary conditions of the establishment?

7. Are the Sanitation SOP records available for FSIS at the start of the same shift the following day?

CSIs will document noncompliance in a manner that accords with Chapter IV of this document.

CSOs

PART I -- Sanitation Performance Standards

There are no written procedures required for meeting the SPS, therefore CSOs do not focus on these regulatory requirements directly. For example, if an establishment is consistently failing the *Salmonella* performance standards, the CSO might be asked to conduct an assessment of the establishment's food safety systems, including whether the establishment is complying with the SPS. In performing this assessment, the CSO should be aware of any problems in complying with the SPS that could be having an impact on food safety. For example, if the CSO found that the employee hygiene and product handling practices were not meeting the regulatory requirements, this failure could be having a direct impact on an establishment's ability to meet the *Salmonella* performance standards. The CSO will document all findings in the Comprehensive Assessment of the Execution and Design of an Establishment's Food Safety Systems, described in Chapter IV of this document.

PART II -- Review of Sanitation SOPs

A. What are the CSO responsibilities?

The CSO systemically looks at the Sanitation SOPs. The CSO will focus on the design of the Sanitation SOPs. The CSO should review the Sanitation SOP and at least 60 days' pre-operational and operational sanitation records and try to answer questions similar to the following:

1. Are the Sanitation SOPs designed to include all procedures necessary to prevent direct contamination or adulteration of product?
2. If the establishment is doing microbiological testing as part of the Sanitation SOP, is the design of the procedure appropriate for the organism?
3. If the establishment has an extended cleanup written in the Sanitation SOP, does the design of the procedure support extended cleanup?
4. If the establishment does microbiological testing to verify the extended cleanup procedure, are the testing procedures designed to find the organisms of concern?
5. If the establishment produces RTE products, are the Sanitation SOPs designed in a manner to prevent cross-contamination from raw to RTE products?
6. If the establishment produces RTE products and includes environmental testing in the Sanitation SOPs, are the procedures designed to

increase testing when significant construction occurs?

7. If there is construction going on in the establishment, have the Sanitation SOPs been designed to identify problems that may emerge as a result of the construction, (sanitary conditions, product contamination)?

8. If environmental testing is included as part of the Sanitation SOPs, are the corrective actions designed to meet the corrective action requirements of section 416.15?

9. If the establishment produces RTE products, are the Sanitation SOPs designed to prevent post lethality contamination from personal hygiene, product handling practices, equipment maintenance, etc.?

B. What do CSOs do after the assessment?

When the assessment of the Sanitation SOPs and a minimum of 60 days of associated records is complete, the CSO is to document a supportable Agency position.

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CHAPTER II - HACCP

I. Introduction

The establishment has the responsibility for complying with 9 CFR Part 417 of FSIS HACCP regulations. 9 CFR 417.2(b) requires that every official establishment develop and implement a HACCP plan covering each product produced by that establishment when the establishment's hazard analysis reveals that one or more food safety hazards are reasonably likely to occur in the process of producing the product.

FSIS has the responsibility for verifying that establishments meet the requirements in 9 CFR Part 417. 9 CFR 417.8 describes the FSIS verification functions that are performed to provide a basis for making determinations as to whether the establishment is in compliance.

CSIs focus on the execution or implementation of the HACCP plan when performing their verification procedures. The CSOs focus more on the design of the HACCP plans when they are conducting an assessment of the HACCP system. The purpose of this section is to set out how each component verifies that establishments are complying with Part 417.

In assessing the adequacy of an establishment's HACCP system, inspection program personnel should consider all of the available evidence.

Inspection program personnel should evaluate their observations and the results of the microbiological sampling that they do in an integrated way. Has the inspector observed a laxness in the establishment's attention to evisceration and its application of its antimicrobial interventions that is reflected in a higher number of positives in the Agency's *Salmonella* sampling? Has the inspector observed a commitment to food safety that produces good results?

Moreover, establishments may do their own environmental testing, testing for APCs or enterobacteriaceae, or other verification testing. Inspection program personnel should ask establishment management whether it does its own testing, and whether it would share the test results. The inspector should make clear that it is in the establishment's interest to be doing and sharing such testing.

For example, an establishment that makes RTE product decides to undertake some in-plant construction. Because construction increases the risk of *L. monocytogenes* contamination of product, the establishment decides to treat this pathogen as a hazard that is reasonably likely to occur, at least during the construction period. Inspection program personnel should seek answers to questions similar to the following to determine whether the establishment's HACCP system is producing safe product.

1. What preventive measures were put in place during the construction to prevent product or product contact surface contamination?
2. Is the plant doing environmental testing during the construction project? If so, do the results indicate any significant micro flora changes during the construction project?
3. Did the establishment implement any additional sanitation procedures during the construction project?
4. Did the establishment do any testing to determine the effectiveness of the special sanitation procedures?

If inspection program personnel determine that product samples should be taken during this period, they should contact the Front-line Supervisor. If the plant is doing such testing and makes the results available to inspection program personnel, it may not be necessary for FSIS to intensify its testing. Inspection program personnel should analyze the results of any testing that has been done for evidence of an emerging problem with *L. monocytogenes* or with an indicator organism that would suggest an emerging *L. monocytogenes* problem. If the establishment is conducting environmental testing and is not willing to share the results, the CSI should contact the Front-line Supervisor.

Each situation is different, and inspection program personnel must use critical thinking in deciding whether there is a basis for concern, or that there is a problem with the establishment's HACCP system that should be addressed. If the establishment is not complying with the regulatory requirements, inspection program personnel should issue an NR or consider recommending other action under the Rules of Practice, 9 CFR part 500 (see Chapter IV).

CSIs

PART I -- HACCP Verification Methodology

A. How do CSIs perform HACCP verification procedures?

The CSI should understand the regulations in 9 CFR part 417, how to apply these regulations in the plant environment, and the appropriate methodology to use in verifying compliance with these regulations. There are two HACCP procedures, an 01 procedure and an 02 procedure, for verifying that an establishment is meeting the regulatory requirements of 9 CFR Part 417. The number of HACCP plans and the number of products produced within a specific processing category has no impact on the number of HACCP procedures that CSIs are scheduled to perform for that process.

NOTE: An establishment can produce many products within the same processing category with one HACCP plan, or can have a separate HACCP plan for each product within that processing category. In either case, there are only two HACCP procedures for that processing category. If the establishment has a separate HACCP plan for each of the products in the same processing category, the CSI needs to have a method of verifying that the regulatory requirements are met in all of the HACCP plans at some frequency. He or she might verify one of the five requirements (monitoring, verification, corrective action, recordkeeping, and reassessment) in all of the HACCP plans for a particular processing category each time the HACCP 01 procedure is performed. Another method he or she might use is to choose a different HACCP plan each time that procedure is to be performed.

There are two components to each of the HACCP procedures, a recordkeeping component and a review and observation component. The CSI can use either of these components or a combination of these components to verify regulatory compliance.

1. The CSI might review the establishment records to verify compliance (recordkeeping).
2. Alternatively or in addition, he or she might take measurements and compare the result with the company records to determine regulatory compliance (review). He or she might also observe an establishment employee perform the activity listed in the HACCP plan to verify regulatory compliance (observation).

The CSI may use any of these components or parts, individually or collectively, to verify regulatory compliance with the HACCP regulations. For example, the CSI can review records at one CCP and take a measurement or observe the establishment take a measurement at another CCP to verify that the monitoring requirement is met.

If the CSI questions the contents of the HACCP plan, he or she should review the hazard analysis and the decisionmaking documents supporting the hazard analysis to verify that the establishment can support the contents of the HACCP plan.

HACCP 01 Procedure

The purpose of the HACCP 01 procedure is to determine if the establishment meets the five regulatory requirements. When the HACCP 01 procedure is scheduled it is used for reviewing a random sample of the HACCP regulatory requirements in operation.

NOTE: The CSI must have a method for randomly selecting the requirements that he or she will verify during the performance of this procedure. After this decision is made, the CSI will need to review the HACCP plan to ensure that he or she has full knowledge of what it contains.

HACCP 02 Procedure

The purpose of the HACCP 02 procedure is to determine if the establishment meets the five regulatory requirements. When the HACCP 02 procedure is scheduled it is used to verify that the establishment is following the HACCP plan, establishment personnel are performing the tasks specified in the HACCP plan, corrective actions are taken, and pre-shipment review prevents the shipment of adulterated product for specific production.

NOTE: The CSI can review records, conduct a measurement, and observe the establishment conducting the activities listed in the HACCP plan. However, the CSI must verify that all the applicable requirements at all of the CCPs have been met for a specific production when performing the HACCP 02 procedure. The CSI can verify corrective actions if there has been a deviation from a critical limit, a deviation not covered by a specified corrective action, or an unforeseen hazard.

When the CSI determines that the establishment does not meet one or more of the regulatory requirements, he or she should document this finding on an NR. If the noncompliance involves the production and shipment of unsafe food, the CSI should initiate the appropriate enforcement actions described in 9 CFR 500.3. He or she should ask the DO to issue an NOIE to the establishment. If the CSI has documented multiple or recurring noncompliances, he or she should contact the DO and request that an NOIE be issued to the establishment as described in 9 CFR 500.4. In other situations the CSI may take a regulatory control action to prevent the shipment of adulterated products. The CSI should also keep the Front-line Supervisor informed of developing trends of noncompliance. (see Chapter IV).

PART II -- Hazard Analysis

A. How do CSIs verify that an establishment has performed a hazard analysis?

During the performance of the 03A01 procedure, CSIs verify that an establishment has performed a hazard analysis as part of its basic compliance with the regulations (9 CFR 417.2(a)). The CSIs should use the thought process and methodology described below when verifying that the hazard analysis complies with the regulation. CSIs will verify compliance by reviewing the flow chart, the hazard analysis, the HACCP plan, the establishment's initial validation of the HACCP plan, and HACCP records.

Before reviewing the hazard analysis, the CSIs should understand that a food safety hazard is defined in 9 CFR 417.1 as *any biological, chemical, or physical property that **may** cause a food to be unsafe for human consumption*. The CSIs must review hazard analysis records to determine whether the analysis considered those properties that have a real chance of occurring in the food or in the processing of the food, and of causing the food to be unsafe. The hazard must be one that would be identified by a reasonable consideration of the food, how it is processed, and where safety issues can arise. The fact that it is possible to imagine a hazard (e.g., a meteor may fall onto the plant) does not mean that the hazard analysis must address that hazard. If the CSI has concerns about whether the relevant hazards have been considered, he or she may decide to discuss issues with the TSC or with the establishment during the weekly meeting. The CSI should ask whether the establishment has considered and addressed the following questions by comparing the hazard analysis to the Basic Compliance Checklist (FSIS Form 5000-1):

1. Did the establishment conduct a hazard analysis or have one conducted for it?
2. Did the establishment's analysis start by identifying all hazards that may occur?
3. Does the hazard analysis identify preventive measures the establishment can apply to the food safety hazards?
4. Does the hazard analysis include a flow chart that describes (diagrams) the steps of each process and production flow in the establishment?
5. Does the hazard analysis identify the intended use or the consumers of the finished product?
6. Does the result of the establishment's hazard analysis reveal that one or more food safety hazards are reasonably likely to occur?

7. Does the establishment have a written HACCP plan for each of its products?

8. Has the establishment conducted validation activities to determine whether the HACCP plan will function as intended?

NOTE: Section 417.4 (a)(1) provides more details about the requirement for initial validation, "... The establishment shall conduct activities designed to determine that the HACCP plan is functioning as intended. During this HACCP plan validation period, the establishment shall repeatedly test the adequacy of the CCPs, critical limits, monitoring and recordkeeping procedures, and corrective actions set forth in the HACCP plan." Validation data for any HACCP plan must include some practical data or information reflecting an establishment's actual experience in implementing the HACCP plan. This is necessary because validation must demonstrate not only that the HACCP plan is theoretically sound, but also that the establishment can implement it and make it work on a day-by-day basis.

9. Do the establishment's records include multiple results that verify the monitoring of CCPs and conformance with critical limits?

10. Does the establishment have subsequent results that support the adequacy of corrective actions in achieving control at a CCP after a deviation from a critical limit has occurred?

B. What happens if the CSI determines that a noncompliance exists?

CSIs will document any noncompliance in a manner that accords with Chapter IV of this document. If the CSI determines that the hazard analysis does not meet the regulatory requirements, he or she should notify the DO for direction. The DO will provide direction to the CSI as to whether he or she should issue a 30-day reassessment letter, or the DO will institute an enforcement action as specified in the Rules of Practice, 9 CFR part 500 (see Chapter IV).

NOTE: An establishment is not required to respond in writing to the 30-day reassessment letter. It is, however, required to address the situation raised in the letter.

PART III -- Monitoring Requirement

A. What is the regulation that applies to monitoring?

9 CFR 417.2(c)(4) - *List the procedures, and the frequency with which those procedures will be performed, that will be used to monitor each of the critical control points to ensure compliance with the critical limits*

B. How do CSIs verify the monitoring requirement?

CSIs verify the monitoring requirement by performing the HACCP 01 or HACCP 02 procedures. CSIs should use the thought process and methodology described below when performing either the HACCP 01 or HACCP 02 procedure. CSIs will verify the regulatory requirement by reviewing the HACCP plan, reviewing HACCP records, observing establishment employees performing monitoring activities, and taking measurements at the CCPs. In verifying the monitoring requirement, the CSI should seek answers to the following questions:

1. Does the HACCP plan list the monitoring procedures and frequencies that are used to monitor each of the CCPs to ensure compliance with the critical limits?
2. Are the monitoring procedures being performed as described in the HACCP plan?
3. Are the monitoring procedures being performed at the frequencies for the CCPs listed in the HACCP plan?

When seeking answers to the above questions, the CSI should:

- a. Review the HACCP plan to determine whether the HACCP plan design includes the monitoring procedures and frequencies that are used to monitor the critical control points. Since the establishment can modify the HACCP plan without notifying inspection program personnel, the CSI should ensure that he or she is familiar with the monitoring procedures and frequencies in the HACCP plan by reviewing the HACCP plan each time he or she verifies the monitoring requirement. When reviewing the monitoring procedures and frequencies in the HACCP plan, the CSI should be able to understand exactly what the establishment is doing at the CCP. If the CSI does not understand how the establishment is performing the monitoring activity at the CCP, he or she will need to determine whether this is an indication that the monitoring requirement is not being met.
- b. Observe an establishment employee performing the monitoring activities listed in the plan to determine whether the procedures are being executed as written in the HACCP plan.
- c. Based on reviewing the monitoring records or on the basis of observing the establishment performing the monitoring procedures, determine whether the monitoring procedures are being performed at the frequencies specified in the HACCP plan.

C. What are some examples of monitoring noncompliance?

- The establishment is not conducting the monitoring procedures as specified in the HACCP plan.
- The establishment is not performing the monitoring procedures at the frequencies specified in the HACCP plan.
- The CSI takes a measurement at a CCP and finds that the critical limit is not met.

CSIs will document any noncompliance in a manner that accords with Chapter IV of this document.

PART IV -- Verification Requirement

A. What are the regulations that apply to verification procedures and frequencies?

9 CFR 417.2(c)(7) – *List the verification procedures, and the frequency with which those procedures will be performed, that the establishment will use in accordance with § 417.4 of this part.*

9 CFR 417.4(a)(2)(i)(ii)(iii) – *Ongoing verification activities include, but are not limited to: The calibration of process-monitoring instruments; direct observations of monitoring activities and corrective actions; and the review of records generated and maintained in accordance with § 417.5(a)(3) of this part.*

B. How do CSIs verify the verification requirement?

CSIs verify the verification requirement by performing the HACCP 01 or HACCP 02 procedures. CSIs should use the thought process and methodology described below when performing either the HACCP 01 or HACCP 02 procedure. CSIs will verify these regulatory requirements by reviewing the HACCP plan, reviewing HACCP records, and observing establishment employees performing verification activities. In verifying the verification requirement, the CSI should seek answers to the following questions:

1. Does the HACCP plan contain procedures and frequencies for the calibration of the process-monitoring instruments?
2. Does the HACCP plan contain procedures and frequencies for direct observations of monitoring activities and corrective actions?
3. Does the HACCP plan list procedures and frequencies for the review of records generated and maintained in accordance with 9 CFR 417.5(a)(3)?

4. Does the HACCP plan list product sampling as a verification activity?
5. Are process-monitoring instrument calibration activities conducted as per the HACCP plan?
6. Are direct observation verification activities conducted as per the HACCP plan?
7. Are records generated in accordance with 9 CFR 417.5(a)(3) being reviewed by the establishment?

When seeking answers to the above questions, the CSI should:

- a. Review the HACCP plan to determine whether it lists direct observation procedures and frequencies, records review procedures and frequencies, and process monitoring calibration verification procedures and frequencies. Since the establishment can modify the HACCP plan without notifying inspection program personnel, the CSI should ensure that he or she is familiar with the verification procedures and frequencies in the HACCP plan by reviewing the HACCP plan each time he or she verifies the verification requirement.
- b. Observe an establishment employee performing the verification activities listed in the plan to determine whether the procedures are being executed as written in the HACCP plan.
- c. Review the HACCP records or observe the establishment performing the verification procedures to determine whether the verification procedures are being performed at the frequencies specified in the HACCP plan.
- d. If the establishment has included an alternative generic *E. coli* sampling frequency into the HACCP plan (see 9 CFR 310.25(a)(2)(iv) or 381.94(a)(2)(iv)), the CSI will verify that the alternative is an integral part of the establishment's verification procedures for its HACCP plan.
- e. If product sampling is included in the HACCP plan, the CSI should observe an establishment employee taking samples and review the results as part of the HACCP 01 or 02 procedures. If the establishment received positive results, the CSI should verify the corrective action requirements of 9 CFR 417.3(b) are met.

NOTE: The CSI should use good judgment in recognizing that there are times when a HACCP plan might not contain all three ongoing verification activities listed in 9 CFR 417.4(a)(2)(i)(ii)(iii). If an establishment has a CCP that is monitored without the use of process monitoring equipment, there would be no need for process monitoring equipment calibration verification procedures. If an

establishment only has one employee, it would not be possible for that person to conduct a direct observation of the monitoring activity. In this situation, the HACCP plan would not need to list a direct observation of the monitoring activities. The direct observation ongoing verification activity should be designed for the plant verifier to directly observe the plant employee conducting the monitoring activity. A plant verifier conducting the same activity as the monitor does not meet the regulatory requirement for the direct observation verification activity described in 9 CFR 417.4(a)(ii).

C. What are some examples of verification noncompliance?

- The HACCP plan does not, at a minimum, list records review verification procedures; direct observation verification procedures; or calibration of process instruments verification procedures.
- The HACCP plan does not list the frequencies at which the verification procedures will be performed.
- The establishment is not performing the direct observation verification procedures as specified in the HACCP plan.
- The establishment is not performing the records review verification procedures as specified in the HACCP plan.
- The establishment is not performing the process monitoring verification procedures as specified in the HACCP plan.
- The establishment is not performing one or more of the verification procedures listed in the HACCP plan at the frequencies specified in the HACCP plan.

CSIs will document any noncompliance in a manner that accords with Chapter IV of this document.

PART V -- Recordkeeping Requirement

A. How do CSIs verify the recordkeeping requirements?

The CSI verifies that the establishment is meeting the recordkeeping requirements. The CSI will verify these requirements by reviewing the HACCP plan, hazard analysis, HACCP records, supporting documentation, and decisionmaking documents. The CSI verifies some of the recordkeeping requirements when performing the HACCP 01 procedure. For example, the CSI uses an 01 procedure to verify that the establishment has supporting documentation for the monitoring procedures in the HACCP plan. Other recordkeeping requirements are verified when performing the HACCP 02

procedure. Preshipment review is verified by performing 02 procedures. The majority of the time the CSI will verify the recordkeeping requirement by reviewing only records (recordkeeping component of the HACCP procedures). An occasion when a CSI may use the review and observation component to verify a recordkeeping requirement is when the CSI observes the establishment actually performing the pre-shipment review. The HACCP procedures that should be used for verification of the recordkeeping regulatory requirements will be specified throughout this section.

B. What is the regulatory requirement for recordkeeping?

9 CFR 417.2(c)(6) – *Provide for a recordkeeping system that documents the monitoring of the critical control points. The records shall contain the actual values and observations obtained during monitoring.*

C. How do CSIs verify compliance with 9 CFR 417.2(c)(6)?

The CSI should review the HACCP plan to verify that it lists the records the establishment will use to document the monitoring of the CCPs. The CSI should review the HACCP records to verify that the establishment is recording actual values and observations that were obtained during the monitoring activities. The CSI should verify these requirements when performing the HACCP 01 procedure and HACCP 02 procedure. In verifying this requirement, the CSI should ask the following questions:

1. Does the HACCP plan set out a recordkeeping system that documents the monitoring of the CCP?
2. Do the records contain actual values and observations obtained during monitoring?

D. What are some examples of noncompliance?

- The HACCP plan does not provide for a recordkeeping system that documents the monitoring of the CCPs.
- The establishment is recording results with a check mark, rather than recording actual values and observations.

CSIs will document any noncompliance in a manner that accords with Chapter IV of this document. CSIs may need to discuss concerns with the establishment and issue a 30-day reassessment letter.

E. What are the requirements for supporting documentation?

9 CFR 417.5(a) – *The establishment shall maintain the following records documenting the establishment's HACCP plan: (1) The written hazard analysis prescribed in § 417.2(a) of this part, including all supporting documentation;*

(2) – The written HACCP plan, including decisionmaking documents associated with the selection and development of CCPs and critical limits, and documents supporting both the monitoring and verification procedures selected and the frequency of those procedures.

NOTE: As part of the requirement above, establishments will have documentation that addresses the requirement in 9 CFR 417.4(a) that "every establishment shall validate the HACCP plan's adequacy in controlling the food safety hazards identified during the hazard analysis." The CSI should determine whether there is compliance with this regulation by verifying that the establishment has the documentation required in 9 CFR 417.5(a)(2)

F. How do CSIs verify compliance with these regulations?

CSIs should verify that there is compliance with these requirements by performing the HACCP 01 procedure. The CSI will verify these requirements by reviewing the hazard analysis, supporting documents for the hazard analysis, HACCP plan, decisionmaking documents associated with the selection and development of the CCPs and critical limits, supporting documentation for the verification procedures and frequencies, and supporting documentation for the monitoring procedures and frequencies. The CSI should use professional judgment on how much supporting documentation to request. The CSI should not just arbitrarily ask for supporting documents. The CSI should request supporting documents when he or she questions whether a decision made by the establishment is the appropriate one.

There are three possible outcomes for the verification of these requirements. Those three outcomes are compliance with the requirements, noncompliance with the requirements, and an inability to determine whether there is compliance because more information is needed. The HACCP 01 procedure is documented as performed when the requirements are met. The CSI issues an NR when there is noncompliance with the requirements. A 30-day reassessment letter should be issued to the establishment when there is not enough information available to determine whether the HACCP plan complies with 9 CFR 417.2. This provides the establishment with an opportunity to support the decisions made, or to reassess the hazard analysis and HACCP plan and make decisions that it can support.

In verifying these recordkeeping requirements, the CSI should seek answers to the following type questions:

1. Does the establishment have the supporting documentation for the decisions made in the hazard analysis?
2. Does the establishment have the decisionmaking documents associated with the selection of each CCP?
3. Do the documents explain why the establishment selected that location for the CCP?
4. Is there a control at the identified point in the process that will prevent, eliminate, or reduce to acceptable levels the identified hazards?
5. Does the establishment have scientific, technical, or regulatory support for the critical limit?
6. Does the support appear credible?
7. Does the establishment have documents supporting the monitoring procedures and frequencies listed in the HACCP plan?
 - a. If the CSI questions the monitoring frequencies, he or she should perform a monitoring check between the scheduled performances of the establishment's monitoring procedure.
 - b. If the CSI finds deviations, and the establishment has not, he or she should verify that the establishment addresses this issue.
8. Does the establishment have documents supporting the verification procedures and frequencies listed in the HACCP plan? Do the documents support what the establishment has done?
9. If the establishment has supporting documents for these decisions, does the documentation support the decisions?

G. What are some examples of noncompliance?

- The establishment has no supporting documentation to support why it is not necessary to establish controls for food safety hazards identified in the hazard analysis.
- The establishment has no decisionmaking documents associated with the selection of the CCPs.

- The establishment has no scientific, technical, or regulatory support for the critical limit.
- The establishment has no documentation supporting the monitoring procedures and frequencies.
- The establishment has no documentation supporting the verification procedures and frequencies.
- The establishment has documentation, but the documentation does not support the decisions made.

NOTE: There are situations when the CSI needs more information to determine whether the establishment is meeting the requirements of 9 CFR 417.2. If the establishment is monitoring its critical limit every hour, and the only supporting documents that are available are the monitoring records for the past year, the CSI might need more information to determine whether the HACCP plan complies with 9 CFR 417.2. The CSI could issue a 30-day reassessment letter requesting that the establishment reassess its HACCP plan. The CSI has not been trained in assessing the scientific and technical information that an establishment might have to support the HACCP system. The CSIs have resources available to assist them in evaluating this information. He or she can contact the TSC, or can contact the DO and request assistance from a CSO.

CSIs will document any noncompliance in a manner that accords with Chapter IV of this document. CSIs may need to discuss concerns with the establishment and issue a 30-day letter.

H. What is the regulatory requirement for HACCP records?

9 CFR 417.5(a)(3) – *The establishment shall maintain: Records documenting the monitoring of CCPs and their critical limits, including the recording of actual times, temperatures, or other quantifiable values, as prescribed in the establishment’s HACCP plan; the calibration of process-monitoring instruments; corrective actions, including all actions taken in response to a deviation; verification procedures and results; product code(s), product name or identity, or slaughter production lot. Each of these records shall include the date the record was made.*

I. How do CSIs verify compliance with 9 CFR 417.5(a)(3)?

CSIs should verify these requirements by reviewing HACCP records that document the monitoring of CCPs and their critical limits, verification procedures and frequencies, and corrective actions taken in response to a deviation from a critical limit, a deviation not covered by a critical limit, or an unforeseen hazard. These requirements can be verified performing the HACCP 01 and HACCP 02

procedures. In verifying these requirements, the CSI should seek answers to the following questions:

1. Do the records document the monitoring of CCPs and their critical limits?
2. Do the records include actual times, temperatures, or other quantifiable values, as prescribed in the establishment's HACCP plan?
3. Do the monitoring, verification, and corrective action records include product codes, product name or identity, or slaughter production lot, and the date the record was made?
4. Are the verification procedures and results of those procedures documented?
5. Is the time recorded when the verification activity was performed?
6. Does the record contain the date the record was made?
7. Are the process-monitoring calibration procedures and results being recorded?

J. What are some examples of noncompliance?

- The records do not have the monitoring results recorded.
- The records do not include actual times that monitoring or verification activities are performed.
- The records include entries such as "acc", "ok", or check marks rather than actual values for monitoring results.
- The monitoring entries do not include product identification or code.
- The records do not include the date the record was completed.
- Initials being recorded rather than the verification procedures and results.
- The corrective actions taken in response to a deviation from a critical limit, other deviation, or unforeseen hazard are not recorded.
- The results of the calibration of process monitoring instruments are not recorded.

CSIs will document any noncompliance in a manner that accords with Chapter IV of this document. CSIs may need to discuss concerns with the establishment and issue a 30-day reassessment letter.

K. What is the regulatory requirement for record authenticity?

9 CFR 417.5(b) – *Each entry on a record maintained under the HACCP plan shall be made at the time the specific event occurs and include the date and time recorded, and shall be signed or initialed by the establishment employee making the entry.*

L. How do CSIs verify compliance with 9 CFR 417.5(b)?

CSIs should verify this regulatory requirement by reviewing HACCP records documenting the monitoring of CCPs and their critical limits, verification procedures and frequencies, and corrective actions taken in response to a deviation from a critical limit or deviation not covered by a critical limit or unforeseen hazard. When verifying this regulatory requirement, the CSI should seek answers to the following questions when performing the HACCP 01 or HACCP 02 procedure:

1. Was each entry on the record made at the time the event occurred?
2. Does each entry include the time?
3. Was each entry on the record signed or initialed by the establishment employee making the entry?

M. What are some examples of noncompliance?

- Some entries on the records do not contain the time the event occurred.
- The records do not include the signature or initials of the person performing the activity.
- There is no date on the records.
- Results are not being recorded when the events occur.

CSIs will document any noncompliance in a manner that accords with Chapter IV of this document. CSIs may need to discuss concerns with the establishment and issue a 30-day reassessment letter.

NOTE: The HACCP monitoring records only need to have the date entered once on the form for all the entries made on that date.

N. What is the regulatory requirement for computerized records?

9 CFR 417.5(d) - *Records maintained on computers. The use of records maintained on computers is acceptable, provided that appropriate controls are implemented to ensure the integrity of the electronic data and signatures.*

O. How do CSIs verify compliance with 9 CFR 417.5(d)?

The CSI can verify this recordkeeping requirement by performing the HACCP 01 or HACCP 02 procedure. The CSI should verify this requirement by requesting that the establishment demonstrate the controls that it has in place to ensure the integrity of the records. When verifying this requirement, the CSI should seek the answer to the following question:

Are appropriate controls provided to ensure the integrity of electronic data and signatures?

P. What are some examples of noncompliance?

- The establishment does not have controls in place to ensure the integrity of the electronic records.
- The establishment has controls to ensure the integrity of the electronic records but is not following those controls, e.g., passwords and electronic signatures are not kept secure.

CSIs will document any noncompliance in a manner that accords with Chapter IV of this document. CSIs may need to discuss concerns with the establishment and issue a 30-day reassessment letter.

Q. What is the regulatory requirement for record retention and availability?

9 CFR 417.5(e)(1)(2)- *Record retention. (1) Establishments shall retain all records required by paragraph (a)(3) of this section as follows: for slaughter activities for at least one year; for refrigerated products, for at least one year; for frozen, preserved, or shelf-stable products, for at least two years. (2) Off-site storage of records required by paragraph (a)(3) of this section is permitted after six months, if such records can be retrieved and provided, on-site, within 24 hours of an FSIS employee's request.*

R. How do CSIs verify compliance with 9 CFR 417.5(e)(1)(2)?

The CSI should verify that the records are being maintained the required amount of time by reviewing the HACCP records. The CSI should not routinely request past records to verify that HACCP records are being maintained for the

appropriate time. If the CSI suspects that records are not being maintained for the required amount of time, he or she should contact the Front-line Supervisor for instructions. The CSI might request records stored off-site one time to ensure they can be provided, but it would not be necessary for the CSI to routinely request records that are stored off-site to verify this requirement. When verifying this recordkeeping requirement, the CSI should seek answers to the following questions performing the HACCP 01 or HACCP 02 procedure:

1. Are the records being maintained for the required amount of time, e.g., 1 year for slaughter and refrigerated products and 2 years for frozen, preserved, or shelf-stable products?
2. Are the records kept on-site for 6 months?
3. If the records are stored off-site after 6 months, can they be retrieved in 24 hours?

S. What are some examples of noncompliance?

- The establishment is not maintaining records for the required length of time.
- The records are not being maintained on premises for 6 months.
- The establishment cannot retrieve the records within 24 hours when stored off-site.

CSIs will document any noncompliance in a manner that accords with Chapter IV of this document. CSIs may need to discuss concerns with the establishment and issue a 30-day reassessment letter.

T. What is the regulatory requirement for pre-shipment review?

9 CFR 417.5(c) – Prior to shipping product, the establishment shall review the records associated with the production of that product, documented in accordance with this section, to ensure completeness, including the determination that all critical limits were met and, if appropriate, corrective actions were taken, including the proper disposition of product. Where practicable, this review shall be conducted, dated, and signed by an individual who did not produce the record(s), preferably by someone trained in accordance with § 417.7 of this part, or the responsible establishment official.

U. How do CSIs verify compliance with 9 CFR 417.5(c)?

FSIS considers product to be “produced and shipped” when the establishment completes pre-shipment review. Verifying that the establishment has completed pre-shipment review enables inspection program personnel to know whether the

company has taken full and final responsibility for applying its HACCP controls to the product that it has produced. The CSI should occasionally perform a verification check by observing the establishment employee perform the pre-shipment review. This type of observation is particularly important if the CSI is new to the establishment. Once the observation verification has been performed, this regulatory requirement can be verified using the recordkeeping component of the HACCP 02 procedure. The CSI should understand that pre-shipment review can be accomplished if the product is at a location other than the producing establishment, as long as the review of appropriate documents and compliance with 9 CFR 417.5(c) occurs before the product leaves the control of the producing establishment.

When verifying an establishment's pre-shipment review of its records by performing the HACCP 02 procedure, the CSI should seek answers to the following questions:

1. Has the establishment reviewed the records associated with the production of the product, prior to shipment?
2. Has the pre-shipment review been signed and dated by an establishment employee?

V. What are some examples of noncompliance?

- The establishment ships the product without conducting a pre-shipment review.
- The establishment performs pre-shipment review but does not sign and date the records.

CSIs will document any noncompliance in a manner that accords with Chapter IV of this document.

PART VI -- Corrective Actions

A. What is the regulation that applies to corrective actions taken in response to a deviation from a critical limit?

9 CFR Part 417.3(a) – *The written HACCP plan shall identify the corrective action to be followed in response to a deviation from a critical limit. The HACCP plan shall describe the corrective action to be taken, and assign responsibility for taking corrective action, to ensure: (1) The cause of the deviation is identified and eliminated; (2) The CCP will be under control after the corrective action is taken; (3) Measures to prevent recurrence are established; and (4) No product that is injurious to health or otherwise adulterated as a result of the deviation enters commerce.*

B. How do CSIs verify compliance with 9 CFR 417.3(a)?

When there is a deviation from a critical limit, the CSI verifies that the requirements of 9 CFR 417.3(a) are met by comparing the corrective actions taken by the establishment to the requirements of the regulation. The CSI should verify that the corrective action requirements are met as part of the HACCP 01 and HACCP 02 procedures. The CSI can verify these requirements by using the recordkeeping component or the review and observation component of the procedures. The corrective action requirements should be verified every time a deviation occurs. To verify compliance with the corrective action regulatory requirements, the CSI seeks answers to the following questions:

1. Did the establishment identify the cause of the deviation?
2. Did the corrective action eliminate the cause?
3. Did the corrective actions ensure that the CCP is brought under control?
4. Were measures implemented to prevent recurrence of the deviation?
5. Did the actions ensure that no product that is injurious to health or otherwise adulterated, as a result of the deviation, enters commerce?

When seeking answers to these questions, the CSI should:

- a. Review the corrective action records associated with the deviation from the critical limit and observe the establishment executing the corrective actions.
- b. Compare the establishment's recorded corrective actions to the regulatory requirements listed in 9 CFR 417.3(a) to determine whether the corrective actions taken in response to the deviation from the critical limit meet all of these requirements.
- c. Observe the establishment executing the corrective actions to verify that the establishment has identified the appropriate affected product.
- d. Observe the establishment executing the corrective actions to verify that the establishment has identified and eliminated the cause of the deviation.
- e. Observe the establishment executing the corrective actions to verify that the establishment's corrective actions have the CCP under control after the actions are taken.
- f. Observe the establishment executing the corrective actions to verify that preventive measures are established.

g. Observe the establishment executing the corrective actions to verify that the establishment prevents product that is injurious to health or otherwise adulterated, as a result of this deviation, from entering into commerce.

C. What are some examples of noncompliance?

- The establishment did not identify the cause of the deviation from a critical limit.
- The establishment identified the cause of the deviation from the critical limit, but did not take appropriate actions to eliminate that cause.
- The establishment did not implement appropriate measures to ensure that the CCP is under control after the actions were taken.
- The establishment did not implement measures to prevent the recurrence of the deviation.
- The establishment did not take appropriate measures to ensure that no product that is injurious to health or otherwise adulterated, as a result of the deviation, enters commerce.

CSIs will document any noncompliance in a manner that accords with Chapter IV of this document. CSIs may need to discuss concerns with the establishment and issue a 30-day reassessment letter.

D. What regulation applies when there is a deviation not covered by a specific corrective action or an unforeseen hazard occurs?

9 CFR 417.3(b) – *If a deviation not covered by a specified corrective action occurs, or if another unforeseen hazard arises, the establishment shall: (1) Segregate and hold the affected product, at least until the requirements of paragraphs (b)(2) and (b)(3) of this section are met; (2) Perform a review to determine the acceptability of the affected product for distribution; (3) Take action, when necessary, with respect to the affected product to ensure that no product that is injurious to health or otherwise adulterated, as a result of the deviation, enters commerce; (4)...*

E. How do CSIs verify compliance with 9 CFR 417.3(b)(1)-(3)?

If an unforeseen hazard occurs, the CSI is to verify that the regulatory requirements of 9 CFR 417.3(b) are met by comparing the corrective actions taken by the establishment with the regulatory requirements in 9 CFR 417.3(b). The CSI should verify that these requirements are met each time there is a deviation not covered by specific corrective actions, or an unforeseen hazard occurs. These requirements should be verified as part of the HACCP 01 or

HACCP 02 procedures. The CSI should answer the following questions to determine whether the corrective action requirements have been met:

1. Did the establishment segregate and hold **all** affected product?

NOTE: To determine what product is affected, consider such factors as the pathogen of concern; the processing and packaging; the equipment; the establishment's testing under its HACCP plan; the establishment's HACCP plan monitoring and verification activities performed in accordance with 417.2 and 417.4; Sanitation SOP records as required in 416.16; and whether some or all of the products controlled by the same or substantially similar HACCP plans have been affected.

2. Did the establishment perform a review to determine the acceptability of the affected product for distribution?

3. Did the establishment take necessary action with respect to the affected product to ensure that no product that is injurious to health, or otherwise adulterated as a result of the deviation, enters commerce?

4. Was a reassessment conducted to determine whether the newly identified deviation or other unforeseen hazard should be incorporated into the HACCP plan?

When seeking answers to these questions, the CSI should:

- a. Review the corrective action records associated with the deviation or unforeseen hazard and observe the establishment executing the corrective actions.

- b. Compare the establishment's recorded corrective actions to the regulatory requirements listed in 9 CFR 417.3(b)(1)(2)(3)(4) to determine whether the corrective actions taken in response to the deviation from the critical limit meet all of these requirements.

- c. Observe the establishment segregating and holding the affected product to verify that the establishment segregated and held **all** affected product.

- d. Observe the establishment evaluating the affected product to verify that only acceptable product is released.

F. What are some examples of noncompliance?

- The establishment did not hold **all** affected product.

- The establishment held product, but it was not the product that was affected.
- The establishment did not evaluate the product to determine whether it was acceptable for distribution.
- The establishment evaluated the product and found it to be unacceptable for distribution, but did not take the necessary action to ensure that no product injurious to health or otherwise adulterated, as a result of this deviation, enters commerce.
- A reassessment was not conducted to determine whether the newly identified deviation or unforeseen hazard should be incorporated into the HACCP plan.

CSIs will document any noncompliance in a manner that accords with Chapter IV of this document. CSIs may need to discuss concerns with the establishment and issue a 30-day reassessment letter.

G. What is the regulation that applies to reassessment when a deviation not covered in the HACCP plan, or an unforeseen hazard occurs?

9 CFR 417.3(b)(4) – *Perform or obtain reassessment by an individual trained in accordance with § 417.7 of this part, to determine whether the newly identified deviation or other unforeseen hazard should be incorporated into the HACCP plan.*

H. How do CSIs verify compliance with 9 CFR 417.3(b)(4)?

The reassessment requirement cannot be randomly verified because reassessment occurs when something triggers it, e.g., a deviation not covered by a specific corrective action or an unforeseen hazard, etc. The establishment is required to document its reassessment when it is triggered by a deviation not covered by a specific corrective action or unforeseen hazard. The CSI should verify that the establishment is meeting the reassessment requirement by reviewing the corrective action records when a deviation not covered by a specific corrective action or unforeseen hazard occurs. When verifying compliance with 9 CFR 417.3(b)(4), the CSI should seek to address the following type questions:

1. Was a reassessment conducted as a result of an unforeseen hazard?
2. Does the establishment have supporting documentation for the decisions made during the reassessment?

I. What are some examples of noncompliance?

- A deviation not covered by a specific corrective action or an unforeseen hazard occurred, and a reassessment was not conducted.
- The establishment conducted a reassessment in response to a deviation not covered by a specific corrective action or an unforeseen hazard and determined that the newly identified deviation or unforeseen hazard should not be incorporated into the HACCP plan, but had no supporting documentation for that decision.

CSIs will document any noncompliance in a manner that accords with Chapter IV of this document. CSIs may need to discuss concerns with the establishment and issue a 30-day reassessment letter.

PART VII -- Reassessment Requirement

A. What is the regulation that applies to reassessment of the HACCP plan?

9 CFR 417.4(a)(3) – Reassessment of the HACCP plan. Every establishment shall reassess the adequacy of the HACCP plan at least annually and whenever any changes occur that could affect the hazard analysis or alter the HACCP plan. Such changes may include, but are not limited to, changes in: raw materials or source of raw materials; product formulation; slaughter or processing methods or systems; production volume; personnel; packaging; finished product distribution systems; or, the intended use or consumers of the finished product. The reassessment shall be performed by an individual trained in accordance with § 417.7 of this part. The HACCP plan shall be modified immediately whenever a reassessment reveals that the plan no longer meets the requirements of § 417.2(c) of this part.

B. How do CSIs verify compliance with 9 CFR 417.4(a)(3)?

The establishment is not required to document reassessments that are conducted as a result of changes in the process, unless the reassessment reveals that modification of the HACCP plan is necessary. If the reassessment reveals that modification of the HACCP plan is necessary, the HACCP plan must be modified immediately, and the HACCP plan must be signed and dated. The establishment is also required to sign and date the HACCP plan to demonstrate that the annual reassessment has been conducted. The CSI should review reassessment records, if available, and the HACCP plan to verify these requirements. When verifying compliance with 9 CFR 417.4(a)(3), the CSI should consider the following questions:

1. Has a reassessment been conducted to meet the annual reassessment requirement?

2. Did the establishment consider any significant developments that have occurred in the plant or that have occurred with respect to the types of products produced by the plant, in its analysis?

3. Has change occurred that could affect the hazard analysis or HACCP plan?

4. Did the establishment reassess?

5. If the reassessment revealed that the HACCP plan no longer meets regulatory requirements, was the HACCP plan modified immediately?

C. What are some examples of noncompliance?

- The annual reassessment was not conducted.
- Reassessment revealed that the HACCP plan no longer meets the requirements of 9 CFR 417.2(c), and the plan was not immediately modified.

NOTE: The establishment can reassess its HACCP plan any time during the calendar year to meet the annual reassessment requirement. This requirement does not require the establishment to reassess every 12 months. The CSI should verify the establishment is meeting the annual reassessment requirement somewhere close to the anniversary date of HACCP implementation in the establishment.

D. What regulation applies to reassessment of the hazard analysis?

9 CFR 417.4(b) – *Reassessment of the hazard analysis. Any establishment that does not have a HACCP plan because a hazard analysis has revealed no food safety hazards that are reasonably likely to occur shall reassess the adequacy of the hazard analysis whenever a change occurs that could reasonably affect whether a food safety hazard exists. Such changes may include, but are not limited to, changes in: raw materials or source of raw materials; product formulation; slaughter or processing methods or systems; production volume; packaging; finished product distribution systems; or, the intended use or consumers of the finished product.*

E. How do CSIs verify compliance with 9 CFR 417.4(b)?

The CSI will have to rely on his or her knowledge of the operation and the changes that occur within that operation. When verifying compliance with 9 CFR 417.4(b), the CSI must answer the following questions:

1. Does the establishment have a process without a HACCP plan because the hazard analysis has revealed there is no food safety hazard likely to occur?
2. Have any changes occurred in the process that could reasonably affect whether a food safety hazard exists?
3. If changes have occurred in the process, has a reassessment been conducted as a result of these changes?

F. What are some examples of noncompliance?

- The establishment has a process with no HACCP plan, changes occurred that could affect whether a food safety hazard exists, and the establishment did not conduct a reassessment of the hazard analysis.
- Changes occurred that could affect whether a food safety hazard exists, reassessment was conducted, the reassessment revealed that a food safety hazard exists, and no HACCP plan was developed.

CSIs will document any noncompliance in a manner that accords with Chapter IV of this document. CSIs may need to discuss concerns with the establishment and issue a 30-day reassessment letter.

G. What regulations apply to reassessment after a B *Salmonella* set failure?

9 CFR 310.25(b)(3)(ii) or 381.94(b)(3)(ii) - *If the establishment fails to meet the standard on the next [second] series of compliance tests for that product, the establishment shall reassess its HACCP plan for that product and take appropriate corrective actions.*

H. How do CSIs verify compliance with 9 CFR 310.25(b)(3)(ii) or 381.94(b)(3)(ii)?

If an establishment fails 2 consecutive *Salmonella* sets (B set failure), it must conduct a reassessment of the HACCP plan for that product. When the CSI is notified that the establishment failed to meet the standard on the second consecutive *Salmonella* set, he or she should verify that the establishment has reassessed its HACCP plan. The CSI should review the hazard analysis, HACCP plan, and supporting documents for the decisions made during

reassessment. When verifying compliance with 9 CFR 310.25(b)(3)(ii) or 381.94(b)(3)(ii), the CSI should seek answers to the following questions:

1. Was a reassessment conducted?

2. If a reassessment was conducted, did the establishment consider *Salmonella* a food safety hazard reasonably likely to occur in that process?

3. If the establishment did not consider *Salmonella* a food safety hazard reasonably likely to occur, does it have documentation to support this decision?

NOTE: CSIs will also work with other program personnel as described in Chapter III, *Salmonella* Performance Standards.

I. What are some examples of noncompliance?

- The establishment failed 2 consecutive *Salmonella* sets, and the HACCP plan was not reassessed.
- The HACCP plan was reassessed and *Salmonella* was not considered a food safety hazard likely to occur, but the establishment has no supporting documents for this decision.

CSOs

PART I – HACCP Assessment

A. What are the CSOs responsibilities for HACCP assessment?

The CSO performs comprehensive assessments of all food safety systems in operation. The focus of the comprehensive assessment is on the design of the food safety systems. For HACCP, the CSO will assess the design of the HACCP plans, microbiological testing protocols, and any other programs that will have an impact on food safety in the establishment.

After the CSO has assessed the systems individually, he or she determines whether the findings from one system correlate to the findings from another, such as investigating whether there is information from sanitation records indicating that there were sanitation problems on a RTE line on the day that the establishment collected a sample of product that tested positive for *L. monocytogenes*.

When the CSO has completed the comprehensive assessment in the establishment, he or she documents an Agency position. The CSO's report is e-mailed to the DO and the Front-line Supervisor. If the CSO finds that the HACCP system does not meet the requirements of 9 CFR 417.2 and 417.5 because of problems with its design or scientific basis, he or she will issue a 30-day reassessment letter to the establishment. If the problems are severe, the CSO may decide to draft an NOIE, for issuance by the DO, or recommend other enforcement actions described in the Rules of Practice, 9 CFR Part 500. The CSO will work with in-plant inspection program personnel to develop a verification plan for any new verification activities that might be necessary as a result of the comprehensive assessment and the corrective actions requested. The Front-line Supervisor will be e-mailed a copy of the verification plan if he or she is not available at the establishment. The Front-line Supervisor and the CSI should contact the CSO any time they have concerns about whether the corrective actions taken by the establishment are adequate to meet the HACCP requirements.

PART II -- Review of the Hazard Analysis

A. How do CSOs assess a hazard analysis?

CSOs will focus on the design of the hazard analysis to verify that it complies with the applicable regulatory requirements. The CSO's data collection and analysis will supplement and add scientific and technical weight to the verification of the in-plant team. The CSO should request records and information from the in-plant team about its verification of the hazard analysis. CSOs should verify

that the establishment has considered food safety hazards that can occur before, during, and after entry of product into the establishment. CSOs will use their scientific knowledge and professional expertise when reviewing the design of the hazard analysis to verify that the establishment has identified the appropriate food safety hazards and preventive measures for those hazards. Some questions that the CSO seeks answers for when reviewing the hazard analysis are:

1. Have the appropriate hazards been considered for the products produced?
2. Have the specific microbial, chemical, and physical hazards been identified that are prevalent to the specific products or process categories?
3. Are there any other hazards that would seem to be relevant that have not been considered?
4. Are the establishment's determinations about hazards that are reasonably likely to occur based on relevant historical data, scientific information, or technical information about the process and a clear understanding of the regulatory standard?
5. Are the controls that the establishment put in place validated, such as by repeated testing of the adequacy of the CCPs and critical limits, and review of records, to ensure that the hazard is prevented, eliminated or reduced to acceptable levels?

B. Have all potential sources of food safety hazards been considered?

The CSO should consider whether all potential sources of food safety hazards have been considered by the establishment, not merely those mentioned in 9 CFR 417.2(a)(3). In making that determination, the CSO should ask whether the establishment has considered and addressed the following questions:

1. Are any of the ingredients likely to present microbial, chemical, or physical hazards?
2. Does the food contain reworked product that might have different microbial, chemical, or physical characteristics than the original ingredients?
3. Does the food permit survival or multiplication of pathogens before or during preparation?
4. Is the product subject to recontamination after the kill step?
5. What is the normal microbial content of the food under proper storage conditions?

6. Under what circumstances will the normal microbial content of the food change?

7. Does the layout of the facility provide an adequate separation of raw materials from RTE food?

8. Will the equipment provide the time/temperature controls necessary for safe product?

9. Does the method of packaging affect the multiplication of microbial pathogens or the formation of toxins?

10. Can the sanitation practices that are employed affect the safety of the food that is being prepared?

11. Do the employees understand the food preparation process and the factors that they must control to ensure safe food?

12. What is the likelihood that the food will be stored at an appropriate temperature?

13. Is the food intended for consumption by a population with increased susceptibility to illness?

14. Will the preventive measures associated with each hazard “prevent, eliminate, or reduce to an acceptable level the hazards the establishment identified in the hazard analysis?”

C. How do CSOs assess the use of prerequisite programs?

When the CSO encounters a hazard analysis in which one or more identified food safety hazards are determined not reasonably likely to occur because of prerequisite programs, the CSO should request access to the prerequisite program as well as recent prerequisite program records to assess the effectiveness of these programs.

The CSO will review the description and features of the prerequisite program, including any supporting documents the establishment has for the criteria in the prerequisite program. The CSO should review such documents to determine whether they support the establishment’s decision that the hazard is not reasonably likely to occur.

The CSO will review data reflecting how the program has operated over a recent period of time and consider whether the control seems to be successful. The CSO should find that the records continue to support the decision that the

hazard is not reasonably likely to occur because of the presence of the prerequisite program.

If an establishment is producing raw ground beef products and has a prerequisite program based on the receipt of purchase specifications, the CSO should review the records associated with such a prerequisite program to verify that the documentation supports the decision made in the hazard analysis that *E. coli* O157:H7 is not reasonably likely to occur.

If the establishment is producing RTE products and has included product or environmental testing in a prerequisite program, the CSO should review the prerequisite program to verify that it is science-based. The CSO will assess the establishment's total system to verify that the establishment has designed its testing procedures so that if indicator organisms or *L. monocytogenes* are detected, the establishment has procedures in place to effectively address their presence. The CSO will review written procedures, assess decisionmaking documents for rationale, and review laboratory results.

The CSO will analyze this data to formulate an Agency position on whether the design of the prerequisite program is appropriate to address the decisions made in the hazard analysis. The CSO should ensure the prerequisite program is working in concert with all the other food safety programs when making this determination.

PART III -- Assessment of Monitoring

A. What does the CSO do to assess monitoring?

CSOs will perform data collection and analysis to verify that the design of the establishment's monitoring procedures, and the frequency with which it performs them, are adequate. The CSO should verify that the monitoring procedures describe a planned sequence of observations or measurements that are to occur at a CCP. The CSO should read the monitoring procedures in the HACCP plan and see whether he or she can visualize the monitoring activity that takes place at that CCP. Most monitoring procedures should be rapid because they relate to "real-time" processes.

The CSO should review a minimum of 60 days monitoring records to assist the CSO in obtaining the following information about the monitoring procedures and frequencies:

1. Are the monitoring frequencies in the HACCP plan continuous?
2. Would it be feasible to have continuous monitoring frequencies?
3. If the monitoring frequencies are not continuous, are they adequate to

demonstrate process control, e.g., statistically based, historically supported, etc.?

4. Is the basis of discontinuous monitoring frequencies documented and appropriate for the HACCP process being verified?

5. Does the establishment review monitoring records to detect trends that can be corrected before the loss of control? If so, the CSO should request to review these records.

6. If the basis for discontinuous monitoring frequencies is not documented, the CSO should determine whether the establishment has supported its frequencies as required by 9 CFR 417.5(a)(2), and if not appropriate, action should be taken, e.g., 30-day reassessment letter should be issued to the plant.

PART IV -- Assessment of Verification

A. How will CSOs assess compliance with the verification requirements?

While the CSI focuses on how an establishment is performing the verification activities outlined in its HACCP plan, CSOs will determine whether an establishment's on-going verification activities comply with regulatory requirements by focusing on the design of on-going verification activities. Consideration of design features should be based on a review of all the verification procedures associated with a single HACCP plan.

B. What records will the CSO review?

The CSO should review records that cover a minimum of 60 days of activity. The CSO should carefully review records of the CCPs, the surrounding verification procedures, the documents justifying their selection, and the frequency of their performance and then consider several analytic questions:

1. Are the verification procedures in the HACCP plan adequately designed for the establishment to determine whether the HACCP system is functioning as intended?

2. What do records reveal about performance at the CCPs?

3. Have there been deviations from critical limits?

4. If there were several deviations from critical limits, was there a reassessment and a new critical limit established? If not, does the establishment have documentation to support this decision?

5. If there were any deviations from critical limits at the CCP, how did the verification procedures contribute to improving the situation?

6. What do the records show about the results of verification?

7. Is the HACCP plan designed to include product testing as a verification procedure?

8. If product testing is a verification procedure listed in the HACCP plan, is this testing program science-based? The frequency and methodology of the testing should be supported in the science-based program (e.g., a rationale when product sampling is triggered—based on the results of food contact surface or environmental testing for an indicator organism; a rationale for sample size – 25 gram food sample; swab area size – along with a rationale for whether composite sampling on a daily or weekly basis is used; a rationale for product action based on indicator and pathogen testing results; a rationale for hold-and-test provisions if a food contact surface is positive for an indicator organism or pathogen). Is the testing designed in a manner to detect the organism of concern?

PART V -- Assessment Activities for Recordkeeping

A. How will CSOs review these recordkeeping activities?

The CSO will assemble the establishment's HACCP records, as specified in 9 CFR 417.5(a)(3) that cover a defined recent period of time.

Using establishment HACCP records only, the CSO should construct a summary of what happened, related to production of safe and wholesome products, in the establishment during that time.

The CSO should discuss with the in-plant inspection team and establishment what could be understood from the records. The in-plant inspection team and the establishment should discuss whether the records reflect what actually happened.

The CSO should also conduct an assessment of the scientific, regulatory, technical, or other supporting documentation. During the assessment of the records the CSO will seek answers to the following type questions:

1. Do the decisionmaking documents support the selection and development of CCPs and critical limits?
2. Do the supporting documents support both the monitoring and verification procedures selected and the frequency of those procedures?
3. Do the decisionmaking documents support the decisions made in the hazard analysis?

4. Does the establishment have documents to support the disposition of affected products?

5. Do the documents support the decisions made during reassessment?

6. If scientific documents are used to support decisions made, has the establishment demonstrated applicability to their in-plant environment?

PART VI -- Assessment of Corrective Actions

A. How do CSOs assess an establishment's corrective actions?

CSOs should select records from at least 60 days of activity to verify the establishment's corrective actions. They should focus the assessment on the design of the corrective actions. CSOs will select a variety of types of critical limits, the corrective actions planned when a deviation occurs and recent records of critical limits, deviations from critical limits, and the corrective actions.

The CSO should seek answers to the following type questions when verifying the corrective action requirement:

1. Did the corrective actions taken in response to a deviation from a critical limit meet the requirements of 9 CFR 417.3?

2. Did the corrective actions taken when a deviation not covered by a specified corrective action occurs, or if another unforeseen hazard arises, meet the requirements of 9 CFR 417.3(b)?

3. Have the corrective actions been effective, i.e., have they resulted in control at the CCP with respect to the critical limit from which there was a deviation? If the records do not demonstrate this control, it is difficult to conclude that the planned corrective actions have met regulatory requirements.

4. Have the preventive measures implemented in the establishment lessened the rate of the deviations from a critical limit?

PART VII -- Reassessment Activities

A. How do CSOs review reassessments?

The CSO should review a minimum of 60 days records to determine if there were situations that occurred that should have triggered a reassessment of the hazard analysis or HACCP plan.

If reassessment has occurred, the CSO should review the establishment's determination made based on the reassessment, and consider the following:

1. Did the establishment change its HACCP plan?
2. What was the basis for its decision?
3. Does it have decisionmaking documents to support making the change, or to support no change, as appropriate?
4. If a change was made, has the establishment validated the change?
5. Does it have supporting documents for the critical limit, the monitoring frequency, etc.?
 - For example, if the establishment produces raw beef products and conducted a reassessment considering the relevant scientific data, the CSO should ask the following questions:
 - a. If the establishment is producing trimmings for ground beef and tests the trimmings for *E. coli* O157:H7, does the establishment conduct a reassessment when a positive result is received?
 - b. Does the establishment producing the trimmings have documentation (scientific, technical) to support the decisions made during the reassessment that the controls in place are adequate to control *E. coli* O157:H7?
 - c. Has the establishment validated the modified HACCP plan by repeatedly testing the adequacy of the CCP, critical limits, monitoring, verification, recordkeeping procedures, and corrective actions set forth in the HACCP plan?
 - d. If the HACCP plan was modified to include microbiological sampling as a verification activity on the effectiveness of the interventions, is the sampling program statistically valid?
 - e. If the establishment did not modify its hazard analysis or HACCP plan as a result of the reassessment, does the establishment have documents to support this decision?
 - If the establishment receives raw beef for grinding and conducted a reassessment considering the relevant scientific data, the CSO should seek answers to the following type questions:
 - a. Does the receiving establishment have purchase specifications requiring all suppliers that determined *E. coli* O157:H7 as a hazard reasonably likely to occur to have one or more CCPs that are validated to eliminate or to reduce *E. coli* O157:H7 below detectable levels, and that verify that these specifications are met?

b. If the establishment considered *E. coli O157:H7* as a hazard likely to occur in the grinding process, are the CCPs designed to control the pathogen?

c. If the establishment decided that *E. coli O157:H7* is not a hazard likely to occur because this pathogen is addressed in prerequisite programs, does the establishment maintain documents setting out the procedures of the prerequisite program and related records as part of the decisionmaking documents?

- If the establishment is producing RTE products, the CSO should review the control measures included in the HACCP plans, Sanitation SOPs, or prerequisite programs. The CSO will review the written procedures, assess decisionmaking documents for completeness and rationale, and review laboratory results. The CSO should seek answers to the following type questions:

a. Has the establishment designed a written science-based program as part of the HACCP plan, Sanitation SOP, or prerequisite program?

b. If the establishment has testing procedures in place for indicator organisms or *L. monocytogenes*, does the establishment have in place procedures to effectively address their presence?

c. If the establishment has testing procedures in place for indicator organisms or *L. monocytogenes*, does the establishment increase its monitoring or verification sampling when significant construction occurs?

d. If the establishment is using an anti-microbial agent in the product in the final packaging to prevent *L. monocytogenes* growth, does the establishment have data to validate it is effective against *L. monocytogenes*?

e. If the establishment has a post-lethality treatment applied, does the establishment have data to validate it is effective against *L. monocytogenes*?

If the CSO observes execution problems during the comprehensive food safety assessment, he or she should document those in the Comprehensive Food Safety Assessment report.

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CHAPTER III - PATHOGEN REDUCTION ACTIVITIES

PART I -- *E. coli* Testing

The purpose of generic *E. coli* testing is to verify the effectiveness of sanitation and process control in slaughter facilities. The following discussion explains how inspection program personnel are to verify that the establishment is maintaining such controls.

A. What is the general requirement for *E. coli* testing?

Section 310.25 states: (a) *“Criteria for verifying process control; E. coli testing.*

(1) *Each official establishment that slaughters livestock must test for Escherichia coli Biotype 1 (E. coli). Establishments that slaughter more than one type of livestock or both livestock and poultry, shall test the type of livestock or poultry slaughtered in the greatest number. The establishment shall:*

(iii) *Maintain records of such analytic results in accordance with paragraph (a)(4) of this section.*

(2) *Sampling requirements.*

(i) *Written procedures.* *Each establishment shall prepare written specimen collection procedures which shall identify employees designated to collect samples, and shall address location(s) of sampling, how sampling randomness is achieved, and handling of the sample to ensure sample integrity. The written procedures shall be made available to FSIS upon request.*

(4) *Recording of test results.* *The establishment shall maintain accurate records of all test results, in terms of CFU/cm² of surface area sponged or excised. Results shall be recorded onto a process control chart or table showing at least the most recent 13 test results, by type of livestock slaughtered. Records shall be retained at the establishment for a period of 12 months and shall be made available to FSIS upon request.”*

B. How will Front-line Supervisors verify the basic requirement of these regulations?

At the time an establishment is granted inspection, the Front-line Supervisor will verify that the written *E. coli* testing procedures meet the basic regulatory requirements. The Front-line Supervisor completes the *E. coli* Basic Compliance Checklist (FSIS Form 5000-3) when performing the 05A01 procedure. This procedure is only performed once. When the procedure is performed, the Front-line Supervisor should use this checklist to verify the written procedures meet the regulatory requirements:

1. Do the written procedures contain procedures for collecting samples for *E. coli* testing?

2. Do the written procedures identify the establishment employee designated to collect the samples for *E. coli* testing?

3. Do the written procedures address the location of sampling?

4. Do the written procedures describe how sampling randomness is achieved?

5. Do the written procedures describe how the samples are handled to ensure sample integrity?

6. Is the establishment collecting samples for *E. coli* testing?

7. Is the establishment recording the analytical results of *E. coli* tests on a process control chart or table?

NOTE: If the Front-line Supervisor performs the 05A01 procedure and determines that the *E. coli* written procedures do not meet regulatory requirements, he or she should meet with establishment management to inform them that they need *E. coli* testing procedures. If the establishment fails to adequately respond to the Front-line Supervisor's request, he or she should contact the DO to inform them of the situation. If there are changes to existing procedures, inspection program personnel are to notify the Front-line Supervisor.

CSIs

PART I – General Procedures for E. coli Testing

A. What general procedures will CSIs follow?

Each official establishment that slaughters livestock or poultry is required to test for *Escherichia coli* Biotype 1. There are 2 procedures (05A01 and 05A02) that CSIs use to verify that these establishments meet the *E. coli* regulatory requirements. CSIs use the 05A01 procedure to verify that the written procedures meet the basic regulatory requirements. The basic regulatory requirements are in 9 CFR 310.25(a)(1) – (4) for livestock slaughter establishments. The basic regulatory requirements for poultry slaughter establishments are set out in 9 CFR 381.94(a)(1) – (4). The regulatory requirements for livestock will be used in this document when the livestock and poultry regulations are the same. When there are differences in the regulations, both regulations will be listed. If CSIs find noncompliances while carrying out the methodologies below, they are to follow the noncompliance determination and documentation instructions in Chapter IV of this document.

B. How will the CSI verify the on-going compliance with 9 CFR 310.25(a)?

The CSI will verify all other requirements when performing the 05A02 procedure. The CSI will utilize FSIS Form 5000-4 to verify that these regulatory requirements are met.

C. How do CSIs verify that establishments are collecting samples from the correct type of livestock or poultry?

When verifying the sample collection requirements, the CSI will seek an answer to the following question: Is the establishment collecting samples from the type of livestock or poultry that it slaughters in the greatest numbers?

D. What is an example of noncompliance?

- The establishment slaughters pork in the greatest numbers but is collecting samples from beef carcasses.

CSIs will document any noncompliance in a manner that accords with Chapter IV of this document.

PART II – Sample Collection

A. What regulations apply to sample collection?

Paragraph 310.25(a)(2)(ii) states: Sample collection. *The establishment shall collect samples from all chilled livestock carcasses, except those boned before chilling (hot-boned), which must be sampled after the final wash. Samples must be collected in the following manner; (A) For cattle, establishments must sponge or excise tissue from the flank, brisket and rump, except for hide-on calves, in which case establishments must take samples by sponging from inside the flank, inside the brisket, and inside the rump. (B) For sheep, goat, horse, mule, or other equine carcasses, establishments must sponge from the flank, brisket, and rump, except for hide-on carcasses, in which case establishments must take samples by sponging from inside the flank, inside the brisket, and inside the rump. (C) For swine carcasses, establishments must sponge or excise tissue from the ham, belly and jowl areas.*

Paragraph 381.94(a)(2)(ii) states: Sample collection. *A whole bird must be taken from the end of the chilling process. If this is impracticable, the whole bird can be taken from the end of the slaughter line. Samples must be collected by rinsing the whole carcass in an amount of buffer appropriate for that type of bird. Samples from turkeys also may be collected by sponging the carcass on the back and thigh.*

B. How will the CSI verify these regulations?

When verifying these requirements, the CSI will seek answers to the following questions:

1. Is the establishment collecting samples at the required location in the process?
2. Is the establishment collecting samples by sponging or excising tissue from the required sites on a livestock carcass, or whole-bird rinsing a chicken or turkey carcass, or sponging a turkey carcass?

C. What are some examples of noncompliance?

- The establishment is not collecting samples from chilled carcasses, and the establishment is not hot boning.
- The establishment is sponging tissue from areas of the carcass other than the flank, brisket, and rump.

CSIs will document any noncompliance in a manner that accords with Chapter IV of this document.

PART III – Sampling Frequency

A. What are the regulations that apply to sampling frequency?

Paragraph 310.25(a)(1)(i) states: Collect samples in accordance with the sampling techniques, methodology, and frequency requirements in paragraph (a)(2) of this section;

Paragraph 310.25(a)(2)(iii) states: Sampling frequency. Slaughter establishments, except very low volume establishments as defined in paragraph (a)(2)(v) of this section, must take samples at a frequency proportional to the volume of production at the following rates:

Cattle, sheep, goats, horses, mules and other equines: 1 test per 300 carcasses, but at a minimum of one sample during each week of operation.

Swine: 1 test per 1,000 carcasses, but at a minimum of one sample during each week of operation.

Paragraph 381.94(a)(2)(iii) states: Sampling frequency. Slaughter establishments except very low volume establishments defined in paragraph (a)(2)(v) of this section, must take samples at a frequency proportional to the establishment's volume of production at the following rates:

Chickens: 1 sample per 22,000 carcasses, but a minimum of one sample during each week of operation.

Turkeys, ducks, geese, and guineas: 1 sample per 3,000 carcasses, but a minimum of one sample during each week of operation.

Paragraph 310.25(a)(2)(iv) states: Sampling frequency alternatives. An establishment operating under a validated HACCP plan in accordance with §417.2(b) of this chapter may substitute an alternative frequency for the frequency of sampling required under paragraph (a)(2)(iii) of this section if,

(A) The alternative is an integral part of the establishment's verification procedures for its HACCP plan and,

(B) FSIS does not determine, and notify the establishment in writing, that the alternative frequency is inadequate to verify the effectiveness of the establishment's processing controls.

Paragraph 310.25(a)(2)(v) states: Sampling in very low volume establishments.

(A) Very low volume establishments annually slaughter no more than 6,000 cattle, 6,000 sheep, 6,000 goats, 6,000 horses, mules or other equines, 20,000

swine, or a combination of livestock not exceeding 6,000 cattle and 20,000 total of all livestock. Very low volume establishments that collect samples by sponging shall collect at least one sample per week, starting the first full week of operation after June 1 of each year, and continue sampling at a minimum of once each week the establishment operates until June 1 of the following year or until 13 samples have been collected, whichever comes first. Very low volume establishments collecting samples by excising tissue from carcasses shall collect one sample per week, starting the first full week of operation after June 1 of each year, and continue sampling at a minimum of once each week the establishment operates until one series of 13 tests meets the criteria set forth in paragraph (a)(5)(i) of this section.

Paragraph 381.94(a)(2)(v) states: Sampling in very low volume establishments. (A) Very low volume establishments annually slaughter no more than 440,000 chickens or 60,000 turkeys, 60,000 ducks, 60,000 geese, 60,000 guineas or a combination of all types of poultry not exceeding 60,000 turkeys and 440,000 birds total. Very low volume establishments that slaughter turkeys, ducks, geese or guineas in the largest number must collect at least one sample during each week of operation, after June 1 of each year, and continue sampling at a minimum of once each week the establishment operates until June 1 of the following year or until 13 samples have been collected, whichever comes first. Very low volume establishments slaughtering chickens in the largest number shall collect one sample per week, starting the first full week of operation after June 1 of each year, and continue sampling at a minimum of once each week the establishment operates until one series of 13 tests meets the criteria set forth in paragraph (a)(5)(i) of this section.

B. How do CSIs verify compliance with these regulations?

When verifying these regulatory requirements, the CSI should seek answers to questions similar to the following:

1. Is the establishment collecting samples at the frequency specified in 9 CFR 310 (a)(2)(iv)?
2. If an establishment is operating under a validated HACCP plan that has substituted an alternative frequency, is the alternative frequency an integral part of the HACCP plan verification procedures?
3. Has FSIS notified the establishment in writing that the alternative frequency is inadequate to verify the effectiveness of process control?
4. If the establishment is sampling based on very low volume, does the volume of animals slaughtered meet the criteria for that sampling rate?

C. What are some examples of noncompliance?

- A swine slaughtering establishment that does not qualify as a very low volume plant is not sampling at the rate of 1 per 1,000 slaughtered or a minimum of one sample each week of operation.
- A chicken slaughtering establishment that does not qualify as a very low volume plant is not sampling at the rate of 1 per 22,000 slaughtered or a minimum of one sample each week of operation.
- An establishment that does not qualify as a very low volume plant is sampling at the rate specified for very low volume rate of slaughter.

CSIs will document any noncompliance in a manner that accords with Chapter IV of this document.

PART IV – Sample Analysis

A. What are the regulatory requirements for sample analysis?

Paragraph 310.25(a)(1)(ii) states: *Obtain analytic results in accordance with paragraph (a)(3) of this section.*

*Paragraph (a)(3) states: Analysis of samples. Laboratories may use any quantitative method for analysis of *E. coli* that is approved as an AOAC Official Method of the AOAC International (formerly the Association of Official Analytical Chemists) or approved and published by a scientific body and based on the results of a collaborative trial conducted in accordance with an internationally recognized protocol on collaborative trials and compared against the three tube Most Probable Number (MPN) method and agreeing with the 95 percent upper and lower confidence limit of the appropriate MPN index.*

B. How do CSIs verify compliance with these regulations?

When verifying these regulatory requirements, the CSI will seek an answer to the following question: Is the laboratory analyzing the samples using an AOAC Official Method or another method that meets the criteria in paragraph (a)(3)?

C. What is an example of noncompliance?

- The laboratory analyzing the samples is not using an AOAC-approved method to obtain analytic results of the *E. coli* samples.

CSIs will document any noncompliance in a manner that accords with Chapter IV of this document.

PART V – Recording of Test Results

A. What are the regulatory requirements for recording test results?

Paragraph 310.25(a)(1)(iii) states: *Maintain records of such analytic results in accordance with paragraph (a)(4) of this section.*

Paragraph (a)(4) states: Recording of test results. The establishment shall maintain accurate records of all test results, in terms of CFU/cm² of surface area sponged or excised. Results shall be recorded onto a process control chart or table showing at least the most recent 13 test results, by type of livestock slaughtered. Records shall be retained at the establishment for a period of 12 months and shall be made available to FSIS upon request.

B. How do CSIs verify compliance with this regulation?

When verifying these requirements, the CSI should seek answers to the following questions:

1. Does the establishment's process control chart or table show at least the most recent 13 *E. coli* results?
2. Does the establishment's process control chart or table express *E. coli* results in terms of CFU/cm² of surface area sponged or excised by type of livestock slaughtered, or CFU/ml of fluid by type of poultry slaughtered?
3. Is the establishment retaining records of test results for 12 months?

C. What are some examples of noncompliance?

- The establishment's process control chart or table does not show the most recent 13 *E. coli* results.
- The establishment's process control chart or table does not express *E. coli* results in CFU/cm² of surface area sponged or excised by type of livestock slaughtered, or CFU/ml of fluid by type of poultry slaughtered.
- The establishment is not retaining records of test results for 12 months.

CSIs will document any noncompliance in a manner that accords with Chapter IV of this document.

PART VI – Evaluation of Results

A. What is the regulatory table for the evaluation of results?

Table 1 – Evaluation of *E. coli* Test Result

| Type of Livestock | Lower limit of marginal range | Upper limit of marginal range | Number of sample tested | Maximum number permitted in marginal range |
|-------------------|-------------------------------|-------------------------------|-------------------------|--|
| | (m) | (M) | (n) | (c) |
| Cattle | Negative | 100 CFU/cm ² | 13 | 3 |
| Swine | 10 CFU/cm ² | 10,000CFU/cm ² | 13 | 3 |
| *Chickens | 100 CFL/ml | 1,000 CFU/ml | 13 | 3 |
| *Turkeys | N.A. ^a | N.A. | N.A. | N.A. |

^a Not available; values for turkeys will be added upon completion of data collection program for turkeys.

* This portion of the Table 1 was extracted from Table 1 of § 381.94(a)(5).

B. How do CSIs verify compliance with this regulation?

If an establishment is sampling for *E. coli* by excising tissue, CSIs should verify that the results comply with the table above. If an establishment is sampling for *E. coli* by sponging carcasses, CSIs should verify that the establishment is evaluating the test results using statistical process control techniques. The CSI should verify that establishments that slaughter turkeys evaluate *E. coli* test results using statistical process control techniques. When verifying these regulatory requirements, the CSI should seek answers to the following questions:

1. If Table 1 does not include applicable m/M criteria, is the establishment using statistical process control techniques to determine what variation in test results is within normal limits?

2. If Table 1 includes applicable m/M criteria, is the establishment determining whether it is operating within these criteria?

C. What are some examples of noncompliance?

- The establishment is sponging livestock carcasses and is not using statistical process control techniques to evaluate *E. coli* test results.
- The establishment slaughters turkeys and is not using statistical process control techniques to evaluate *E. coli* test results.

CSIs will document any noncompliance in a manner that accords with Chapter IV of this document.

CSOs

PART I -- Assessment of Establishment's *E. coli* Process?

A. What are the CSOs responsibilities?

The CSOs should assemble and review the following information:

1. The results of verification procedures conducted by the CSIs.
2. The written *E. coli* procedures.
3. Justification for an alternative sampling frequency, if applicable.
4. Laboratory information or assurances about methodology.
5. Records of recent test results.

The CSO may also verify elements of sampling procedures by observing establishment employees performing them, if practicable. The CSO should analyze this information and determine whether there is compliance with 9 CFR 310.25(a) (1) – (4) or 381.94(a)(1) – (4).

If there has been a recent verification procedure by the in-plant team, and the results from this verification are different from those of the CSO, the CSO should initiate a meeting to resolve these differences. The CSOs should collect test data results covering at least 60 days.

The CSO should review these data against the evaluation criteria, which may be m/M values or values established by statistical process control. If any of the criteria are not met, the CSO is to conduct further data collection and analysis to determine whether the Agency needs to take other action to ensure that all applicable provisions of the law are met.

If the CSO observes that the evaluation criteria are not met routinely, the testing records should be supplemented with records of fecal NRs or deviations from the zero tolerance critical limit for the same time period. If the Agency was sampling and testing for *Salmonella* during the 60-day period, the CSO should seek those results. If by chance the establishment's product was sampled and tested for *E. coli* O157:H7 or implicated in a recall during the same 60-day period, the CSO should seek those results as well.

The CSO should perform statistical tests to define any correlations among the assembled data sets. If there are no significant correlations, the CSO need not pursue this analysis any further. If there are significant correlations, the CSO needs to analyze them to determine whether regulatory requirements are being met.

Whether the data sets show significant correlations or not, if there were NRs for fecal contamination or deviations from fecal critical limits, shortly before or during the 60-day period, the CSO should seek the corrective action records for each such instance and verify them.

The CSO may want to discuss the generic *E. coli* testing results that do not meet the criteria with establishment officials, to see if they have any views about what might have caused them, and anything they may have done to improve the situation.

***Salmonella* Performance Standards**

PART I -- *Salmonella* Set Failures

The *Salmonella* performance standard is designed to verify that establishments are controlling pathogens in their operation. See FSIS Directive 10,011.1 for instructions on how FSIS inspection program personnel are to do sampling for *Salmonella*. The following discussion explains what will occur if an establishment fails a sample set.

A. What happens if there is an A set failure?

The DM will send a letter to the establishment with the following information:

1. The set completion date as listed on the PREP report,
2. class of product,
3. sample test results (e.g., number of samples analyzed and number of positive samples),
4. a statement that the establishment needs to take immediate action to meet the standard in accordance with sections 310.25(b)(3)(i) or 381.94(b)(3)(i) of the regulations,
5. a request for the establishment to respond to the SVMO/IIC with an explanation as to why it believes that it is operating in full compliance with the regulations or on what immediate actions it intends to take.

Within 30 days of the date of the DM's letter:

1. The SVMO/IIC will document the establishment's response to the DM's letter (i.e., corrective actions identified or an explanation of why the establishment believes that it is in compliance). The SVMO/IIC will maintain a copy of the documentation in the inspection files.
2. The Front-line Supervisor and SVMO/IIC will conduct and document an assessment of the establishment's HACCP and Sanitation SOP procedures and, where applicable, analyze data from the establishment's generic *E. coli* testing, focusing on the corrective and further planned actions by the establishment. The SVMO/IIC will maintain a copy in the inspection files.
3. The Front-line Supervisor and SVMO/IIC will develop, document, and implement a plan, using the 01 and 02 Sanitation SOP and HACCP procedure codes, to verify any corrective actions implemented by the establishment (verification plan). The SVMO/IIC will maintain a copy in the inspection files.

4. After the SVMO/IIC and Front-line Supervisor have completed the above documents, as needed, the Front-line Supervisor will forward them to the DM.

The Front-line Supervisor and SVMO/IIC will correlate with in-plant inspection program personnel to ensure the plan is understood and executed. Based on findings of the verification activities, enforcement actions, if warranted, will be taken in accordance with the rules of practice. The Front-line Supervisor will inform the DM about any necessary enforcement action.

The Front-line Supervisor, SVMO/IIC, and in-plant inspection program personnel will consult with the TSC for any needed assistance in data analysis or technical questions that may arise.

The DM should ensure that collection of samples for the B set begins immediately after an establishment has completed its corrective and preventive actions or within 60 days of the end of the A set unless he or she has agreed with the establishment that more time is needed for corrective and preventive actions to be implemented. The DM, in communication with the Front-line Supervisor and SVMO/IIC should make sure that the establishment is progressing in a timely manner with their actions.

B. What happens if there is a B set failure?

The DM will send a letter to the establishment with the specific sample information as discussed above. The letter will inform the establishment that FSIS expects the establishment to address its total food safety program by reassessing its HACCP plan for that product and taking the appropriate corrective and preventive actions and making any necessary corrective actions in its Sanitation SOPs.

The DM, in consultation with the Front-line Supervisor, SVMO/IIC, and inspection program personnel, will determine whether the establishment conducted proper reviews of its total food safety program, including a reassessment as defined under 9 CFR 417.4(a)(3), Reassessment of HACCP plans, and any necessary evaluation of the effectiveness of the Sanitation SOPs as defined in 9 CFR 416.14, Maintenance of Sanitation SOPs. The DM will issue an NOIE as set out in the rules of practice if the reassessment is not performed.

After the establishment has performed a reassessment, validated modifications to the plan, and reevaluated and modified as appropriate the Sanitation SOPs, the DM will initiate an IDV review, as set out in FSIS Directive 5500.1 paragraph X. As provided for in FSIS Directive 5500.1, a CSO will be a member of this IDV team. The DM will receive the report developed from the IDV, which contains the team's findings. The DM's designee will analyze the findings and make recommendations to the DM about how to proceed. Also, at this point

for grinding establishments, FSIS may decide to conduct an IDV at some or all of the establishment's suppliers.

The DM will make one of the following decisions:

1. If the establishment's actions addressing its total food safety program do not meet the requirements in the regulations, based on the analysis and the supporting information, the DM will issue an NOIE.

2. If the establishment's actions addressing its total food safety program raise concerns regarding the establishment's design and execution of the program, but the concerns do not lead to a determination that there are regulatory noncompliances, the DM will send a 30-day reassessment letter that outlines his or her concerns. The 30-day reassessment letter will ask the establishment to produce records (9 CFR 417.5(a), Records and 9 CFR 416.16, Recordkeeping Requirements) that address the concerns identified by inspection program personnel in the letter.

3. If the establishment's actions addressing its total food safety program in response to the IDV meet the requirements in the regulations, or if in response to the NOIE or the 30-day reassessment letter, the establishment provides adequate evidence that it has not failed to meet the requirements in the regulations, the DM will schedule a C set to verify the successful operation of the establishment's total food safety program.

The CSO will take the lead in developing a verification plan to be used by in-plant inspection program personnel to verify all modifications made by the establishment in response to the B set failure and, if warranted, to assess corrective actions and further planned actions provided in response to an enforcement action. The CSO will send a copy of the verification plan to the Front-line Supervisor and DM and a copy will be maintained in the inspection files at the establishment. The verification plan will be based on the Sanitation SOP and HACCP 01 and 02 inspection procedures.

The CSO, Front-line Supervisor, SVM/O/IIC, and in-plant inspection program personnel will correlate to ensure the plan is fully understood and executed as intended.

The Front-line Supervisor will e-mail a report in a Word document to the DM each month on the findings of the verification activities until the establishment has passed the next *Salmonella* sample set.

The DM should ensure that collection of samples for the C set begins immediately after an establishment has completed its corrective and preventive actions or within 90 days of the end of the B set unless he or she has agreed with the establishment that more time is needed for modifications to be implemented.

The DM, in communication with the Front-line Supervisor and SVM/O/IIC should make sure that the establishment is progressing in a timely manner with their actions.

C. What happens if there is a C set failure?

The DM will send a letter to the establishment with the specific sample information, as discussed above. The letter will inform the establishment that FSIS will instruct a CSO and a Compliance Officer to conduct a focused assessment of the establishment's total food safety program to investigate the reasons why, in light of previous reassessments and corrective actions, the establishment failed a C set. (NOTE: For slaughter operations, the DM will consult with Headquarters.)

The CSO and a Compliance Officer will focus their assessment on the reassessments and corrective and preventive actions that the establishment took after the B set failure, and on whether there is a basis in accordance with the rules of practice to find that the establishment's total food safety program is not adequate. The CSO and the Compliance Officer will consult with the SVM/O/IIC and the Front-line Supervisor. If the establishment requests, the CSO and the Compliance Officer will meet with the establishment and provide it with an opportunity to present evidence as to why it believes that it has not failed to meet the requirements in the regulations. The Compliance Officer will begin to develop a case file for an enforcement action if warranted. This file should include any information presented at the meeting with the establishment. Also, at this point for grinding establishments, FSIS may decide to conduct an IDV at some or all of the establishment's suppliers.

Based on findings of the CSO and the Compliance Officer, the DM and officials from headquarters will determine what actions the Agency will take, including enforcement actions, in accordance with the rules of practice.

There may be rare instances in which, based on the CSO and Compliance Officer findings, the DM determines that the establishment should conduct an additional reassessment. In such cases, the DM will issue a 30-day reassessment letter, and program personnel will conduct in-plant verifications and follow-up verification testing will occur.

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CHAPTER IV - ENFORCEMENT

CSIs

PART I – FSIS Form 5400-4, Noncompliance Record (NR)

Noncompliance Records (NR) are the forms completed by inspection program personnel and issued to the establishment when there is a failure to comply with regulatory requirements. The following discussion explains how to complete an NR.

A. How are the blocks on the NR and NR Continuation Sheet completed in the PBIS Electronic format or in instances when the electronic format is not accessible, on the paper FSIS Forms 5400-4 and 5400-4a?

Type of noncompliance

Food Safety

Any 01 - SSOP

Any 03 - HACCP

06D01 – Sanitation Performance

Standards

05A01 - micro. sampling for *E. coli*

05A02 - micro. sampling for *E. coli*

05A03 - micro. sampling for *Salmonella*

05B02 - Directed sampling

05C01 - Residue

Other Consumer Protections

Any 04 - Economic/Wholesomeness

05B01 - Economic Sampling- Scheduled

06D02 – Inspection Requirements

BLOCK

1. **Date**--Enter the date noncompliance occurred. The date can be entered numerically, e.g., 1-29-02.

2. **Record No.**--Number the NRs completed in a given establishment sequentially, by year (i.e., 1-02, 2-02, 3-02, etc., for the paper forms regardless of who completes the NR).

3. **Est. No.**--Enter as a 5-digit number followed by a red meat or poultry designator and the shift number (e.g., 00345 M/2).

4. **To (Name and Title)**--Enter the name and title of the responsible establishment official. For a HACCP system noncompliance, always enter the name of the person who signed the HACCP plan. For a Sanitation SOP regulation noncompliance, always enter the name of the person who signed the

Sanitation SOPs. For SPS noncompliance, the CSI should enter the name of the establishment official responsible for responding to the NRs.

5. **Personnel Notified**--Enter the name of the establishment management personnel who was/were notified about the noncompliance.

6. **Relevant Regulations**--Cite the specific regulatory requirements that the establishment did not meet. For example, if the establishment did not take corrective action in response to a deviation from a critical limit, then 417.3 (a) would be entered.

7. **Relevant Section/Page of Establishment Procedure/Plan**—Enter the section or page of the establishment’s procedure or plan when the noncompliance represents the failure to comply with the written provisions of their procedure or plan. For example, if the monitoring frequency listed in the HACCP plan is hourly, and the establishment performs the procedure every two hours, there is monitoring noncompliance. Inspection program personnel record the section or page of the HACCP plan that lists the monitoring frequency. Place an “X” in the appropriate box to reference the type of procedure or plan. *E. coli* and alternate processing procedure noncompliance are considered “other.” When the noncompliance is not related to a procedure or plan, enter N/A.

8. **ISP Code**--Enter the code of the procedure performed (refer to: FSIS Directive 5400.5; Attachment 6, Inspection System Procedure Guide for a listing of codes).

9. **Noncompliance Classification Indicators**--Mark the classification trend indicator that best describes the noncompliance. This should be the same classification trend indicator that is circled when inspection program personnel complete the related FSIS Form 5400-2; Procedure Schedule. For basic compliance procedures (01A01, 03A01, and 05A01), no trend indicator is marked.

10. **Description of Noncompliance**—Describe each noncompliance in clear, concise terms, including the exact problem, its location, and the effect on product. For example, if the CSI observes condensation dripping from the ceiling onto exposed product, the description should include the area of the plant where the observation was made, what type of product was being contaminated, and the action taken. If there is a trend of noncompliance developing, and the current NR is linked to previous NRs, the CSI should list the previous NRs with the similar noncompliance from the same cause. The NR should state what corrective actions were proposed, and that these actions were ineffective or not implemented. If this developing trend has been discussed with establishment management, this information should also be documented in this block. If more space is needed to describe the noncompliance, use a NR Continuation Sheet.

11. **Signature of Inspection Program Employee**--The IIC or CSI signs the NR after blocks 1 through 10 have been completed.

12 & 13. **Plant Management Response**--The "immediate action" and "further planned action" blocks should be completed. When the establishment elects to respond, the "immediate action" is the action the establishment is taking to correct the noncompliance including appropriate product disposition. The "further planned action" is the action to prevent recurrence. Inspection program personnel should document an oral response by the plant management.

14 & 15. **Signature of Plant Management and Date**--If establishment management responds in writing on block 12 or block 13, an establishment official should sign and date the NR.

16 & 17. **Verification Signature of Inspection Program Employee and Date** --*The IIC or CSI signs after inspection program personnel have verified the establishment has brought itself into compliance with the regulatory requirement that resulted in the issuance of the NR and if necessary the NR Continuation Sheet.*

B. How can FSIS personnel write a good NR?

- Clearly and concisely identify each noncompliance. Be descriptive, specific and thorough, including time and location.
- Explain that the establishment management has received adequate oral and written notification.
- Include:
 - The inspection findings,
 - Any previous corrective actions that were unsuccessful, and
 - Any applicable deadlines.
- Set out the establishment response to previous notification.
- If a regulatory control action is taken, reflect the use.

C. How is the continuation sheet completed?

In addition to the NR, there is a Continuation Sheet, FSIS Form 5400-4a, that is used only when the inspection program personnel need extra space, or when multiple inspection program personnel conduct verification of pre-operational sanitation inspection procedures in elements 01B and 01C. When using the NR

Continuation Sheet for extra space, inspection program personnel can just check the box next to the word "Attachment" in the top right corner of the sheet, and complete blocks 1-3,10,11 and 12.

PART II -- Documentation of SPS Noncompliance

A. What are the general procedures for documenting the SPS verification activities?

The CSI performs ISP procedure 06D01 to verify compliance with the SPS regulations. Noncompliance is the failure of an establishment to meet one or more regulatory requirements. Every time the CSI finds that the establishment is not meeting the SPS requirements, he or she should document the noncompliance on an NR. If the noncompliance is failure by the establishment to comply with the SPS, the Food Safety block is checked on the NR.

There are four trend indicators associated with procedure 06D01. Those trend indicators are lighting, structural, outside premises, and product based. Only one of these trend indicators can be used for each NR issued. If more than one trend indicator applies, the CSI should use the most appropriate one to describe the noncompliance. If the determination has been made that there is regulatory noncompliance, the CSI should include the regulation citation in Block 6 of the NR.

B. When is the lighting trend indicator used?

The lighting trend indicator is used when there is noncompliance with lighting requirements. If inadequate light causes the quality or intensity of lighting to be inadequate to determine whether the products are being processed, handled, stored, or examined under sanitary conditions, and thus whether the product is not adulterated, the lighting trend indicator should be marked on the NR (see Chapter I, Part IV).

NOTE: The CSI should realize that there might be less than perfect situations that do not constitute noncompliance. If one light is inoperable, but its absence does not cause the intensity or quality of the lighting to be inadequate to determine whether the products are being processed, handled, stored, or examined under sanitary conditions, and thus whether the product is not adulterated, there is no noncompliance.

C. When is the structural trend indicator used?

The structural trend indicator is used when structural regulatory requirements are not met. The CSI should use the structural trend indicator when structural noncompliances are observed, such as holes in the wall, cracks or holes in the

floor, or condensation on overheads that create insanitary conditions or could result in product adulteration (see Chapter I, Part III).

D. When is the outside premises trend indicator used?

The outside premises trend indicator is used when the CSI finds that the regulatory requirements for outside premises are not met. For example, the CSI should use the outside premises trend indicator when he or she observes an accumulation of trash or rubbish outside the establishment that permits harborage and breeding of pests (see Chapter I, Part II).

E. When is the product based trend indicator used?

The product based trend indicator is used when there is noncompliance involving product that does not result in misbranding, mislabeling, or direct product contamination that is covered by the Sanitation SOPs. For example, the CSI observes product from the previous day's production on a wall before the start of operations that creates an insanitary condition, he or she should use the product based trend indicator (see Chapter I, Part XII).

F. What actions should be taken when noncompliance with the SPS regulations is observed?

If an establishment has not complied with a sanitation performance standard, and product is not directly contaminated, CSIs need to determine whether the noncompliance requires a regulatory control action to prevent contamination or adulteration of product.

1. If there is an imminent probability that the noncompliance will result in product adulteration if not addressed immediately, CSIs will take a regulatory control action such as tagging product or rejecting equipment and complete a NR.

2. If the noncompliance does not need immediate attention, CSIs are to notify the establishment management of the noncompliance and document the finding on a NR.

If an establishment has not complied with a sanitation performance standard, and product is directly contaminated, CSIs will verify that the establishment addresses the noncompliance by meeting the requirements of 9 CFR 416 or 9 CFR 417 as described below. CSIs will write an NR using the appropriate 01 (Sanitation SOP) or 03 (HACCP) ISP procedure code.

1. If direct product contamination occurs, CSIs will verify that the establishment implements corrective actions, including product control actions, that meet the requirements of 9 CFR 416.15. The establishment may need to re-

evaluate the effectiveness of its Sanitation SOPs and modify them if they are no longer effective in preventing direct contamination or adulteration of product.

2. If the direct product contamination poses a food safety hazard, CSIs will verify that the establishment implements corrective actions, including product control actions, that meet the requirements of 9 CFR 417.3(b). These corrective actions include a reassessment to determine whether the unforeseen hazard should be incorporated into the HACCP plan.

PART III -- Documentation of Sanitation SOP Noncompliance

A. What do CSIs document?

The CSI performs the Sanitation SOP verification procedures to verify that the establishment is meeting the regulatory requirements of 9 CFR 416.12 – 416.16. When the CSI determines that the establishment does not meet one of these regulatory requirements, he or she should document the noncompliance on an NR, marking the most appropriate trend indicator and the food safety box.

The four trend indicators for Sanitation SOP are:

1. monitoring,
2. implementation,
3. recordkeeping, and
4. corrective actions.

NOTE: Only one trend indicator should be used for each NR issued.

B. When is the monitoring trend indicator used?

The CSI should mark the monitoring trend indicator on the NR when he or she determines that the plant fails to monitor its pre-operational or operational sanitation procedures daily or at the frequency specified in the Sanitation SOP. When the CSI observes contaminated product or contaminated direct contact surfaces that the establishment monitoring did not detect, the monitoring trend indicator is used (see Chapter I, Part XIV).

C. When is the corrective action trend indicator used?

The CSI should mark the corrective action trend indicator when the establishment does not meet the corrective action requirements. This trend indicator should be marked on the NR when the establishment does not take corrective actions to meet the requirements in 9 CFR 416.15. This trend

indicator should be used when FSIS determines that the corrective actions taken are not adequate to restore sanitary conditions. It would be the appropriate trend indicator to use if the establishment did not implement measures adequate to prevent recurrence. If the establishment did not implement corrective action to ensure appropriate disposition of contaminated product, this would be the appropriate trend indicator (see Chapter I, Part XVI).

D. When is the recordkeeping trend indicator used?

The CSI should use the recordkeeping trend indicator when there is noncompliance with 9 CFR 416.16. This trend indicator would be marked when the records are not being maintained daily or retained for the required period of time, or the plan fails to record the results of the monitoring check. This is the appropriate trend indicator to use when the establishment is not documenting the corrective actions taken when FSIS or the establishment determines the Sanitation SOP did not prevent direct contamination or adulteration of product. This trend indicator would also be marked on the NR when the records have not been initialed and dated (see Chapter I, XVII).

E. When is the implementation trend indicator used?

The CSI uses the implementation trend indicator when he or she finds two regulatory requirements that have not been met during the performance of one procedure. For example, if the CSI is performing the 01C02 procedure and finds that the establishment is not monitoring the operational procedures at the stated frequency and did not initial and date the daily sanitation records, the appropriate trend indicator to use is implementation.

F. What actions do CSIs take when noncompliance with the Sanitation SOPs is observed?

When the CSI is performing the 01B02 or 01C02 Sanitation SOP procedure and observes direct contact surfaces or product that is contaminated, he or she should take a regulatory control action on the equipment or product. He or she should not remove the regulatory control action until the establishment has proposed corrective actions that 1) ensure appropriate disposition of products, 2) restore sanitary conditions, and 3) prevent recurrence of direct contamination or adulteration of products. The CSI documents the noncompliance on the NR. If the CSI is performing the 01B01 or 01C01 Sanitation SOP procedure and observes that the establishment official responsible for the implementation and monitoring of the Sanitation SOP did not initial and date the record, the CSI documents the noncompliance on the NR, although no regulatory control action would be required.

NOTE: If the establishment has found the noncompliance and taken the corrective actions required, there is no noncompliance. The CSI should verify

that the establishment is implementing the corrective actions specified in 9 CFR 416.15 when the establishment finds direct contamination or adulteration of products or contact surfaces. If the establishment finds that the responsible individual did not initial and date the record and implemented immediate and further planned actions and records these actions, the CSI should not document this as noncompliance.

G. What actions do CSIs take when noncompliance is found with both SPS and Sanitation SOP regulatory requirements?

If the CSI is performing one of the sanitation procedures (06D01, 01B02, 01C02) and observes noncompliance with the SPS and Sanitation SOP regulatory requirements, all of the findings would be documented under the appropriate Sanitation SOP procedure. If the CSI is performing the 01B02 or 01C02 procedure and only observes noncompliance with the SPS regulations, he or she should document the Sanitation SOP procedure as performed on the Procedure Schedule, and issue a NR under the 06D01 procedure. If the CSI is performing the 06D01 procedure and only observes Sanitation SOP noncompliance, he or she should document the 06D01 procedure as performed and issue a NR for the Sanitation SOP noncompliance using the appropriate procedure (01B02 or 01C02).

PART IV -- HACCP Noncompliance Determinations

A. What is the difference between a deviation from a critical limit and HACCP noncompliance?

A deviation from a critical limit is the failure to meet the applicable value determined by the establishment for a CCP. If a deviation from a critical limit occurs, an establishment is required to take actions in accordance with 9 CFR 417.3.

A HACCP noncompliance is the failure to meet any of the regulatory requirements of 9 CFR part 417, monitoring, verification, recordkeeping, reassessment, and corrective action. If a HACCP noncompliance occurs, an establishment is expected to take immediate and further planned actions to correct the noncompliance.

B. What should CSIs consider before making a noncompliance determination?

Before making a determination that there has been noncompliance, consider the following questions:

1. Has the establishment already identified the failure to meet the regulatory requirements or deviations from critical limits?

2. If product is involved, has the establishment ensured product safety?

3. Has the establishment taken immediate and further planned actions to correct the failure to meet regulatory requirements, or has it taken the 9 CFR 417.3 corrective and preventive measures to address the deviations?

4. Is a trend developing (i.e., has the establishment repetitively carried out the actions in 1 through 3 above for similar situations)?

NOTE: In answering these questions, it may be necessary to consider additional records.

If the answer is no to questions 1, 2, or 3, or yes to question 4, then a noncompliance exists. CSIs will write an NR and perform a HACCP 02 procedure.

If the answer is yes to 1 through 3 and no to question 4, then there is no noncompliance because the establishment has already identified and addressed the situation. The HACCP 01 should be considered performed, and no other action is necessary. Because the establishment's response provides the further planned actions and preventive measures for the noncompliance or deviation, not writing an NR does not adversely affect an inspection program employee's ability to track developing trends. However, an establishment's failure to follow through on further planned actions and preventive measures could lead to recurring noncompliances and would warrant NRs in recurring situations.

C. What are some situations that CSIs may encounter that will require a determination as to whether there is a noncompliance?

NOTE: For purposes of consistency, all the examples below use a monitoring example. The methodology applies to problems with verification, recordkeeping, reassessment and corrective actions as well.

EXAMPLE 1: While performing the HACCP 01 procedure records review, an inspector finds that an establishment employee missed a 9:00 a.m. monitoring check. The inspector then finds that the establishment found the error during its records verification, demonstrated product safety with other records, and took immediate corrective and preventive measures for the noncompliance by re-training the employee. Also, the inspector looked at previous NRs and determined that the establishment had not missed a monitoring check in over three months. In this situation no NR is necessary even though there was a missed monitoring check, and the HACCP 01 procedure is marked as performed. However, if the inspector finds that adequate preventive measures were not in place, and that the missed monitoring check and correction had occurred several times within the month, he or she may determine that a trend for monitoring

noncompliance has developed. In this case he or she will issue an NR and discuss this trend with establishment management during the weekly meeting.

EXAMPLE 2: While performing the HACCP 01 procedure records review, an inspector finds that an establishment employee missed a 9:00 a.m. monitoring check and finds no indication that the establishment identified the missed monitoring check. He or she writes an NR for the HACCP 01 procedure. Then he or she performs a HACCP 02 procedure and finds that the product was shipped without a pre-shipment review. In this situation the inspector writes an NR that explains this noncompliance. Next he or she determines whether the establishment can provide other documentation that establishes product safety. If the establishment cannot demonstrate product safety, the inspector would take action under the Rules of Practice, 9 CFR part 500.

EXAMPLE 3: While performing the HACCP 01 procedure records review, an inspector observes that an establishment employee recorded a deviation from a critical limit on the monitoring record. The inspector verifies that the corrective actions taken by the establishment meet the requirements of 9 CFR 417.3(a). There is no regulatory noncompliance, and an NR is not necessary.

EXAMPLE 4: While performing the HACCP 02 procedure records review for a single lot of product, an inspector sees in the records that an establishment employee missed a monitoring check at 10:00 a.m. and had a deviation from a critical limit at 11:00 a.m. The inspector continues to review the records and finds that at pre-shipment review the establishment identified the deviation and took the proper 9 CFR 417.3 corrective and preventive measures but failed to address the monitoring error. In this situation the inspector writes an NR for the monitoring error and determines whether the establishment can demonstrate product safety relevant to the missed monitoring check. If so, no other action is necessary. If the establishment cannot support product safety, the inspector should take action in accordance with the Rules of Practice, 9 CFR part 500.

D. How do CSIs document a HACCP noncompliance?

The CSI performs the HACCP verification procedures to verify that the establishment is meeting the regulatory requirements of 9 CFR 417.2 – 417.7. The five requirements that the CSI verifies when performing these procedures are **monitoring, verification, corrective actions, recordkeeping, and reassessment**. When the CSI performs one of the HACCP procedures and determines that there is regulatory compliance, he or she documents that the procedure is performed on the procedure schedule. When the CSI determines that the establishment does not meet one of the regulatory requirements, he or she documents the noncompliance on an NR, marking the appropriate trend indicator. The four trend indicators for HACCP are monitoring, corrective action, recordkeeping, and establishment verification. Only one trend indicator should be used for each NR issued.

E. When do CSIs use the monitoring trend indicator?

A CSI should use the monitoring trend indicator when he or she determines that there is noncompliance with the monitoring requirement. This trend indicator should be marked: 1) if the CSI determines the establishment is not monitoring the critical limit at the frequency stated in the HACCP plan; 2) if the CSI determines the establishment is not monitoring the critical limit using the procedures described in the HACCP plan; or 3) if the CSI finds a deviation from the critical limit that the establishment has no way of detecting (see Chapter II, Part III).

F. When do CSIs use the verification trend indicator?

The CSI should use the establishment verification trend indicator when: 1) the establishment is not conducting the verification activities as described in the HACCP plan, or 2) the establishment is not conducting the verification activities at the frequencies described in the HACCP plan (see Chapter I, Part IV).

G. When do CSIs use the corrective action trend indicator?

The corrective action trend indicator should be used when a deviation or an unforeseen hazard occurs, and the corrective action taken by the establishment does not meet the regulatory requirements. The CSI should use the corrective action trend indicator if the corrective actions taken in response to a deviation from a critical limit did not: 1) appropriately address identifying and eliminating the cause of the deviation; 2) include measures to ensure that the CCP is under control; 3) include measures to prevent the deviation or unforeseen hazard from recurring; or 4) include appropriate disposition of the product (see Chapter I, Part VI).

NOTE: For this trend indicator, the CSI is only to document an establishment's failure to meet the requirements of 9 CFR 417.3. If the establishment finds the deviation or unforeseen hazard and takes the corrective action necessary to meet the regulatory requirements, there is no noncompliance.

H. When do CSIs use the recordkeeping trend indicator?

The CSI should use the recordkeeping trend indicator when: 1) The monitoring records do not include the actual times, temperatures, or other quantifiable values, the calibration of process-monitoring instruments, corrective actions, verification procedures and results, product identity, signature or initials of the person making the entry, or the date the record is made; 2) the establishment does not have the decisionmaking documents associated with the selection and development of the CCPs and critical limits, and documents

supporting both the monitoring and verification procedures and frequencies; 3) the establishment did not conduct pre-shipment review; or 4) the establishment is not retaining HACCP records for the required length of time (see Chapter I, Part V).

PART V -- *E. coli* Noncompliance Determination

A. How do the CSIs determine noncompliance?

When the CSI performs the 05A02 procedure (see Chapter III), noncompliance exists if he or she determines that:

1. The establishment is not collecting samples from the type of livestock or poultry that it slaughters in the greatest number.
2. The establishment is not collecting samples at the location in the slaughter process required by the regulations.
3. The establishment is not collecting samples by sponging or excising tissue from the required sites on a livestock carcass, whole-bird rinsing or sponging on the required sites of a turkey carcass or whole-bird rinsing chickens.
4. The establishment is not collecting samples at the required frequency.
5. The establishment is not sampling randomly as per its written procedure.
6. The establishment is not having the samples analyzed at a laboratory using an AOAC Official Method or another method that has been approved and published by a scientific body.
7. The establishment's records of test results do not include at least the most recent thirteen test results.
8. The establishment's records do not express *E. coli* test results in terms of colony forming units per square centimeter when excision tests are used for cattle and swine or sponge tests are used for cattle, swine, or turkeys; or test results are not expressed in colony forming units per milliliter when the whole bird rinse method is used.
9. The establishment is not retaining records of test results for twelve months.
10. Table 1 in the regulations does not include applicable m/M criteria, and the establishment is not using a statistical process control technique to determine how much variation in test results is within normal limits.

11. Table 1 in the regulations includes applicable m/M criteria, and the establishment is not determining whether it is operating within these criteria.

B. How will the CSI document findings?

When the CSI makes the determination that one or more of the above requirements are not met, the CSI should document the noncompliance on an NR. The “other” trend indicator is always used with the 05A02 procedure.

PART VI -- Linking NRs

A. When should NRs be linked?

The CSI should only link NRs when the noncompliances are from the same cause. For example:

- If repetitive condensation findings are occurring, the CSI should be linking NRs together to document that there is a trend occurring. This trend may be because the preventive measures are either not implemented or are ineffective in preventing this noncompliance. However, a CSI should use professional judgment in making the determination whether NRs should be linked. If the establishment has shown a substantial period of compliance, the CSI should not link the NR to previous NRs with the same cause, unless there is a compelling circumstance that justifies doing so, for example, the exact same circumstance that brought about the initial NR has reoccurred.
- An NR under procedure 06D01 for condensation can be linked to an NR written for condensation under procedure 01B02 or 01C02 as the cause is the same. However, an NR written for condensation under 06D01 should not be linked to an NR written for water dripping from the ceiling, from a roof leak, under 06D01. They are both noncompliances and both are water dripping from the ceiling. Both are documented under the same procedure code and the same trend indicators. However, the noncompliance for condensation is from a different cause than the noncompliance for the roof leak.

When the CSI links one NR to another, he or she should reference the previous NR number and date as well as the further planned action that was ineffective in preventing recurrence of the noncompliance. For example:

- The CSI issued NR 25-02 on July 1, 2002, for condensation and the establishment installed fans as its further planned action. On July 8, 2002, the CSI again observes condensation. If the CSI links these NRs, he or she should document in Block 10, that the same or similar noncompliance was documented on July 1, 2002, on NR 25-02. The further planned

action of installing fans was ineffective in preventing the condensation noncompliance.

When the CSI starts linking NRs, he or she should be discussing these linkages with plant management during the weekly meetings. The CSI should also include in Block 10 of the NR that these discussions were held.

The purpose of linking NRs is to provide notification to the establishment that the further planned actions have been ineffective in, or were not implemented in a way that is, preventing the noncompliance from recurring, and that if the trend continues, the repetitive NR would support an enforcement action under the rules of practice.

The CSI should also include a statement in Block 10 of the NR stating that continued failure to meet regulatory requirements can lead to enforcement actions described in 9 CFR 500.4.

The CSI should continue to link NRs together that derive from the same or a related cause until he or she determines that an enforcement action is necessary to bring the establishment into compliance with the regulations. When the determination is made by the CSI that enforcement action is necessary, he or she should contact the DO and ask the DO to issue an NOIE to the establishment, as described in 9 CFR 500.4. The CSI should always keep his or her supervisor apprised of the situation.

NOTE: It is important to note that noncompliance with SPS requirements can be linked to Sanitation SOP or HACCP noncompliance if the cause of the noncompliance is the same. It is inappropriate for the CSI to have several NRs documenting noncompliance without linkage and then determine there is a trend occurring and list all of the individual NRs to serve as linkage. The NRs should be linked as they are issued, and the concern communicated to the establishment at the weekly meetings.

The CSI should use good judgment in making the determination which NRs to link together. For example:

- If the CSI observes condensation on an overhead that is not contaminating product and makes the determination there is SPS noncompliance, he or she should then determine whether there is a need to link that NR to a previous NR.
- One of the decisions that the CSI needs to make when trying to reach this determination is whether the second noncompliance is an isolated incident or a trend of noncompliance developing. Some of the questions that might assist the CSI to make this decision are:

1. How much time has lapsed since the previous NR was written?
2. Was this noncompliance from the same cause as the previous NR?
3. Were the establishment's further planned actions implemented?
4. Were the establishment's further planned actions effective in reducing the frequency of these noncompliances?
5. Is the establishment continuing to implement better further planned actions?

- An establishment might have several hundred pieces of equipment that are cleaned daily prior to operation. The procedures have been implemented as per the Sanitation SOP, the monitoring of the procedures have been conducted, but there may still be a small amount of residue on a contact surface somewhere in the plant at some frequency that was not found during the establishment's monitoring. To determine whether a trend is developing, the CSI would ask:

1. Are the noncompliances occurring due to the same cause?
2. Why are the noncompliances occurring? (Negligence, ineffective method, incomplete execution by the plant, or some other reason)

NOTE: The CSI can contact the supervisor for assistance in making this decision. The in-plant inspection team can also contact the TSC for assistance, if needed.

B. What is the difference between the use of trend indicators and deciding that two NRs can be linked?

Trend indicators are used on NRs to note that the noncompliance is of a particular type. The fact that two NRs have the same trend indicator marked does not necessarily have any regulatory significance. The noncompliances that are the subject of the NRs may or may not be related. NRs are to be linked when the noncompliances are from the same cause.

CSOs

PART I -- FSIS Form 5000-8, Comprehensive Assessment of the Execution and Design of an Establishment's Food Safety Systems Report

A. What FSIS Form do CSOs complete after performing a comprehensive assessment of establishments food safety systems?

CSOs complete FSIS Form 5000-8. CSOs can find this electronic form in the Public Folders/All Public Folders/Agency Issuances/Forms/5000 Series. The CSO can access this form and save it to a disk, or can open and complete the form and save the information as a file.

CSOs are only to include the facts that they observe during the plant visit, and they are to document these facts in a manner that will allow anyone reading the report to understand the observations that were made.

B. How do CSOs complete FSIS Form 5000-8?

In the first portion of the form, CSOs are to fill in the appropriate information in the blocks provided (i.e., establishment number, dates of the establishment visit, name and address of establishment, name of CSO, district, circuit visited, and reason for visit).

In the second portion of the form, CSOs provide a summary of the data assessment they compiled prior to visiting the establishment (e.g., the type of data analyzed and a brief summary of the analysis of the data).

In the third portion of the form, CSOs provide findings and recommendations. CSOs are to include:

1. A summary of the entrance meeting
2. Specific findings about design and execution elements

NOTE: CSOs are only to record facts, not suppositions or opinions. CSOs should not include solutions to findings.

3. A recommendation such as issuance of a 30-day letter or a NOIE

NOTE: The CSOs are to document the findings in a manner that explains the basis for the recommendation.

4. A summary of the exit meetings with establishment management and with in-plant personnel (e.g., attendees, main findings, recommended actions, CSO

contact for design issues, Front-line Supervisors responsible for execution of the systems, and what resources were provided to the establishment).

C. What is the distribution of the completed form?

After CSOs complete the form, they are to e-mail it to the DM and the Front-line Supervisor. The DM will file the report in a District Public Folder.

Rules of Practice

PART I -- Enforcement Actions

A. What are the three types of enforcement actions defined in the Agency's Rules of Practice?

9 CFR 500.1 defines three types of enforcement actions. They are :

1. A "regulatory control action," is the retention of product, rejection of equipment or facilities, slowing or stopping of lines, or refusal to allow the processing of specifically identified product;

2. A "withholding action," is the refusal to allow the marks of inspection to be applied to products. A withholding action may affect all product in the establishment or product produced by a particular process; and

3. A "suspension," is an interruption in the assignment of program employees to all or part of an establishment.

B. Although similar, what are the differences between a withholding action and a suspension?

Withholding actions affect whether the mark of inspection may be applied, while suspensions affect whether inspection verification activities will be performed.

Both withholding and suspension actions are different from a withdrawal of a Federal grant of inspection or a refusal to grant inspection. Withdrawal actions are initiated by the FSIS Administrator according to the Department of Agriculture's Uniform Rules of Practice, a different set of procedures, found at 7 CFR Subtitle A, part 1, subpart H.

PART II -- Regulatory Control Action

A. What are the regulatory provisions for a regulatory control action?

9 CFR 500.2 lists the reasons for which FSIS may decide to take a regulatory control action. They are:

- 1. insanitary conditions or practices;*
- 2. product adulteration or misbranding;*

3. conditions that preclude FSIS from determining that product is not adulterated or not misbranded; or

4. inhumane handling or slaughtering of livestock.

B. What is the purpose of a regulatory control action?

A regulatory control action covers a wide variety of inspection procedures.

A regulatory control action is a limited focus action that is to be used to address specific problems that inspection program personnel come upon in the course of their activities.

A regulatory control action permits inspection program personnel to identify regulatory noncompliance and prevent the movement of the product involved or use of the equipment or facility involved until the noncompliance has been corrected. Inspection program personnel are not required to give the establishment prior notification that they are about to execute a regulatory control action.

C. What are some examples of regulatory control actions?

- A regulatory control action may be warranted for direct product contamination with a contaminant that does not result in a food safety hazard.
- A regulatory control action may be warranted with respect to product that is economically adulterated.
- A regulatory control action may also be warranted as a result of regulatory noncompliance even when there is no product contamination or adulteration.
- A regulatory control action should be taken when inspection program personnel are assessing sanitary conditions of the establishment prior to operation and observe product residue from the previous day's production on a contact surface.
- A regulatory control action would be warranted if inspection program personnel determine that packaged product does not meet the net weight requirements.
- Inspection program personnel could initiate a regulatory control action when there is noncompliance with the SPS regulations, if control is needed to prevent contamination of product.

NOTE: Regulatory control actions are not frequently used for HACCP regulatory noncompliance unless control is necessary to prevent shipment of contaminated or adulterated product.

D. What procedures are to be used when inspection program personnel take a regulatory control action?

After determining that a regulatory control action needs to be taken, inspection program personnel will notify, as specified in 9 CFR 500.2(b), the establishment orally or in writing of the action and the basis for it. The written notification will be a NR.

As specified in 9 CFR 500.2(c), an establishment may appeal a regulatory control action by following the procedures described in 9 CFR 306.5 and 381.35. These simple procedures direct establishments that want to appeal to bring the appeal to the next level of supervision.

PART III -- Withholding Actions and Suspensions

A. When is prior notification not necessary before taking a withholding or suspension action?

9 CFR 500.3, states that *“FSIS may take a withholding action or impose a suspension without providing the establishment prior notification because*

- 1. The establishment produced and shipped adulterated or misbranded product as defined in 21 U.S.C. 453 or 21 U.S.C. 601;*
- 2. the establishment does not have a HACCP plan as specified in 417.2;*
- 3. the establishment does not have Sanitation SOPs as specified in 416.11-416.12;*
- 4. sanitary conditions are such that products in the establishment are or would be rendered adulterated;*
- 5. the establishment violated the terms of a regulatory control action;*
- 6. an establishment representative assaulted, threatened to assault, intimidated, or interfered with an FSIS employee; or*
- 7. the establishment did not destroy a condemned meat or poultry carcass, or part or product thereof in accordance with part 314 or part 381, subpart L of this chapter, within three days of notification.*

NOTE: As a suspension only under 9 CFR 500.3(b), the establishment is handling or slaughtering animals inhumanely.

B. Why is prior notification not necessary?

The situations in paragraph III A necessitate prompt action to protect the public health or the safety of FSIS personnel. When this is the case, but only in such cases, a withholding action or suspension action may be taken without prior notification.

Inspection program personnel taking withholding actions without prior notification must be able to document the imminent threat to public health or to the safety of inspection program personnel that made prior notification infeasible.

NOTE: Multiple instances of economic adulteration do not justify taking a withholding action without prior notification to the establishment and the opportunity to achieve compliance.

C. When is prior notification necessary before taking a withholding action or a suspension action?

9 CFR 500.4 states that *FSIS may take a withholding action or impose a suspension after an establishment is provided prior notification and the opportunity to demonstrate or achieve compliance because:*

- 1. The HACCP system is inadequate under 417.6 of this chapter, due to multiple or recurring noncompliances;*
- 2. The Sanitation Standard Operating Procedures have not been properly implemented or maintained as specified in 416.13 through 416.16 of this chapter;*
- 3. The establishment has not maintained sanitary conditions as prescribed in sections 416.2 – 416.6 of this chapter due to multiple or recurring noncompliances;*
- 4. The establishment did not collect and analyze samples for E. coli Biotype I, and record results in accordance with 310.25(a) or 381.94(a) of this chapter; or*
- 5. The establishment did not meet the Salmonella performance standard requirements prescribed in 310.25(b) or 381.94(b) of this chapter.*

D. What is the purpose of the prior notification?

The purpose of prior notification, with an opportunity for the establishment to respond, is to provide the establishment with due process procedures.

For paragraph C above, the determinations require that the Agency compile extensive information and analyze it with care and good judgment. This makes it reasonable to provide the establishment with this information in advance. The establishment will have an opportunity to point out any factual errors made by the Agency, identify scientific or technical disagreements, and articulate differing interpretations of regulatory requirements. All this information is useful to FSIS in determining how to proceed. The plant also has an opportunity to present corrective actions.

PART IV – NOTIFICATION

A. How is an establishment notified if FSIS decides to take a withholding action or impose a suspension?

As stated in 9 CFR 500.5(a) *If FSIS takes a withholding action or imposes a suspension, the establishment will be notified orally and, as promptly as circumstances permit, in writing. The written notification will:*

- a. state the effective date of the action(s),*
- b. describe the reasons for the actions(s),*
- c. identify the products or processes affected by the action(s),*
- d. provide the establishment an opportunity to present immediate and corrective action and further planned preventive action; and*
- e. advise the establishment that it may appeal the action as provided in sections 306.5 and 381.35 of this chapter*

B. How is the establishment notified when it is necessary for FSIS to provide the prior notification to the establishment that there is a basis for FSIS to withhold the marks of inspection or to suspend inspection as specified in 9 CFR 500.4?

9 CFR 500.5 (b) states: *The prior notification provided for in section 500.4 of this part will:*

- a. state the type of action that FSIS may take;*
- b. describe the reasons for the proposed action;*
- c. identify the products or processes affected by the proposed action;*

d. advise the establishment of its right to contact FSIS to contest the basis for the proposed action or to explain how compliance has or will be achieved; and

e. advise the establishment that it will have three business days from receipt of the written notification to respond to FSIS unless the time period is extended by FSIS.

To meet the notification requirements of 9 CFR 500.5, a DM issues an NOIE to an establishment. In addition to informing an establishment about noncompliances warranting a withholding or suspension, the NOIE provides an establishment three business days to contest the basis for the proposed enforcement action or to demonstrate how compliance has been or will be achieved. Based on discussion with the establishment, the DM may extend the three business days if he or she believes this is necessary.

NOTE: An establishment may appeal all aspects of inspection decisions, including the issuance of the NOIE. However, an appeal of the NOIE is not a separate action, and the establishment is expected to make such an appeal as part of its response to the NOIE.

C. What should a DM do when he or she receives an establishment's response to an NOIE?

The DM should assess and evaluate the establishment's response and decide whether inspection should be withheld or suspended. The DM determines whether the establishment's proposed action plan addresses the problem and, if implemented, is likely to provide an acceptable solution. The DMs should consider any decisionmaking documents as required by the appropriate regulations. Also, the DM should consider the establishment's history of implementing its operating procedures and its planned corrective and preventive actions and determine whether the establishment is likely to implement its proposed actions effectively. DMs are encouraged to contact staff members from the TSC, the Office of Public Health and Science, and the Office of Policy and Program Development for assistance in making decisions.

Upon assessing and evaluating the establishment's response, the DM may decide to accept the establishment's plan, implement the appropriate enforcement action, or defer his or her decision. The following provides the DM guidance on what procedures to follow:

1. Under what circumstances should a DM accept the establishment's response?

If the establishment responds within the specified time frame, has demonstrated that compliance has already been achieved, or provides a

description of acceptable corrective and preventive actions from which the DM can find that compliance will be achieved upon implementation, the DM can accept the response, notify the establishment of the decision, ensure that the establishment implements the corrective and preventive actions in a timely manner, and close the matter with a letter of information to the establishment.

2. Under what circumstances could a DM implement an enforcement action?

If the establishment does not respond or, based on the DM's assessment and evaluation of all pertinent information, the DM finds that compliance cannot or will not be achieved upon implementation, the DM will implement the enforcement action. In those instances involving:

- withholding actions, the DM instructs the IIC to impose the withholding action and notifies the establishment as specified in 9 CFR 500.5(a). The DM's notification must include the basis for his or her decision.
- suspension actions, the DM instructs the IIC to suspend inspection and notifies the establishment as specified in 9 CFR 500.5(a). The DM's notification must include the basis for his or her decision.

D. Under what circumstances can a DM defer an enforcement decision?

A DM may defer an enforcement decision when he or she has substantial reason to believe that the establishment's proposed corrective and preventive action are adequate to eliminate the noncompliance but lacks the substantive and supporting evidence that he or she needs to make a definite decision. For example, a plant may submit an apparently adequate proposed plan and have a good history of executing its HACCP plan, but not include sufficient documentation to enable the DM to find that the proposed plan, once executed, will prevent recurrence. In this situation, a DM may choose to defer his or her enforcement decision and allow the establishment to implement the plan until it can be determined whether the plan is effective. The DM is expected to make a decision on the adequacy of the preventive action as soon as sufficient information becomes available. The DM should not defer a decision for more than 90 days without cause. The DM is to notify the establishment in writing as to why he or she deferred a decision.

If the DM determines that the establishment's plan is adequate, the DM should close the matter with a letter of information to the establishment.

If, at any time, during a period of deferment, the establishment fails to adhere to the proposed action plan, and the DM determines that an enforcement action is warranted, the DM will instruct the IIC to either impose a withholding action or effect the suspension in accordance with 9 CFR 500.4. The DM will immediately

notify the establishment management of this decision and the basis for it in accordance with 9 CFR 500.5.

PART V -- Abeyance

A. What is an abeyance, and when is it used?

9 CFR 500.5(e) states that *FSIS may hold a suspension in abeyance and allow the establishment to operate under the conditions agreed to by FSIS and the establishment.*

B. Under what circumstances could the DM hold a suspension in abeyance?

When a DM has suspended inspection, he or she may subsequently decide to hold that suspension in abeyance as specified in 9 CFR 500.5 if:

1. the establishment presents a plan that demonstrates to the satisfaction of the DM that the establishment has designed corrective and preventive actions that are appropriate to meet the regulatory requirement; and

2. it is necessary to allow the establishment to operate after implementing these corrective and preventive actions so the DM can determine whether the establishment is able to adequately execute the plan. The DM should not hold a suspension in abeyance until the corrective and preventive actions are implemented, and the abeyance should not be for more than 90 days without cause.

If the establishment has a history of failing to meet the criteria discussed above, the DM may decide not to accept the establishment's plan.

If the DM decides to put the suspension in abeyance, and the establishment fails to either meet regulatory requirements or maintain regulatory compliance, during the abeyance period, the DM may lift the abeyance and put the suspension back in effect. If this occurs, the DM will instruct the IIC to suspend inspection in accordance with 9 CFR 500.4 and immediately notify the establishment management in accordance with 9 CFR 500.5(a). The DM will also contact the Acting Regional Investigation Manager.